HEMISPHERX BIOPHARMA INC
Form 10-K
March 16, 2009

FORM 10-K
SECURITIES AND EXCHANGE COMMISSION
[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2008
OR
[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission File No. 1-13441

HEMISPHERX BIOPHARMA, INC.
(Exact name of registrant as specified in its charter)

Delaware 52-0845822 _
(State or other jurisdiction of (I.R.S. Employer Identification
incorporation or organization) Number)

1617 JFK Boulevard Philadelphia, Pennsylvania 19103 _
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (215) 988-0080

Securities registered pursuant to Section
12(b) of the Act:

Common Stock, $.001 par value

Securities registered pursuant to Section 12(g) of the Act:
(Title of Each Class)
NONE

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ( ) No (X)

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ( ) No (X)

Indicate by check mark whether the registrant (1) has filed all reports to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes (X) No ( )

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ( )

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one): ( ) Large accelerated filer(X) Accelerated filer ( ) Non-accelerated filer ( ) Smaller Reporting Company ( )

Indicate by check mark whether the registrant is a shell company (as defined in

Rule 12b-2 of the Exchange Act). Yes ( ) No (X)

The aggregate market value of Common Stock held by non-affiliates at June 30, 2008, the last business day of the registrant's most recently completed second fiscal quarter was $59,326,916.

The number of shares of the registrant's Common Stock outstanding as of March 3, 2009 was 80,881,135.

DOCUMENTS INCORPORATED BY REFERENCE: None.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K (the "Form 10-K"), including statements under "Item 1. Business," "Item 1A. Risk Factors," "Item 3. Legal Proceedings" and "Item 7. Management's Discussion and Analysis of Financial Condition and Result of Operations," constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995 (collectively, the "Reform Act"). Certain, but not necessarily all, of such forward-looking statements can be identified by the use of forward-looking terminology such as "believes," "expects," "may," "will," "should," or "anticipates" or the negative thereof or other variations thereon or comparable terminology, or by discussions of strategy that involve risks and uncertainties. All statements other than statements of historical fact included in this Form 10-K regarding our financial position, business strategy and plans or objectives for future operations are forward-looking statements. Without limiting the broader description of forward-looking statements above, we specifically note that statements regarding potential drugs, their potential therapeutic effect, the possibility of obtaining regulatory approval, our ability to manufacture and sell any products, market acceptance or our ability to earn a profit from sales or licenses of any drugs or our ability to discover new drugs in the future are all forward-looking in nature.

Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Hemispherx Biopharma, Inc. and its subsidiaries (collectively, "Hemispherx", "we or "us") to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements and other factors referenced in this Form 10-K. We do not undertake and specifically decline any obligation to publicly release the results of any revisions which may be made to any forward-looking statement to reflect events or circumstances after the date of such statements or to reflect the occurrence of anticipated or unanticipated events.

PART I

ITEM 1. Business.

GENERAL

We are a biopharmaceutical company engaged in the clinical development, manufacture, marketing and distribution of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. The Company was founded in the early 1970s doing contract research for the National Institutes of Health. Since that time, we have

established a strong foundation of laboratory, pre-clinical, and clinical data with respect to the development of nucleic acids to enhance the natural antiviral defense system of the human body and to aid the development of therapeutic products for the treatment of certain chronic diseases. We have three domestic subsidiaries BioPro Corp., BioAegean Corp., and Core BioTech Corp., all of which are incorporated in Delaware and are dormant. The Company's foreign subsidiary is Hemispherx Biopharma Europe N.V./S.A. established in Belgium in 1998, which has limited or no activity. All significant intercompany balances and transactions have been eliminated in consolidation.

Our current strategic focus is derived from four applications of our two core pharmaceutical technology platforms Ampligen(R) and Alferon N 2
Injection(R). The commercial focus for Ampligen(R) includes application as a treatment for Chronic Fatigue Syndrome (CFS) and as a vaccine enhancer (adjuvant) for both therapeutic and preventative vaccine development. Alferon N Injection(R) is an FDA approved product with an indication for refractory or recurring genital warts. Alferon(R) LDO (Low Dose Oral) is an application currently under early stage development targeting influenza and viral diseases both as an adjuvant as well as a single entity anti-viral.

Ampligen(R) is an experimental drug currently undergoing clinical development for the treatment of CFS. In August 2004, we completed a Phase III clinical trial ("AMP 516") treating over 230 CFS patients with Ampligen(R) and are presently in the registration process for a new drug application ("NDA") with the Food and Drug Administration ("FDA"). Over its developmental history, Ampligen(R) has received various designations, including Orphan Drug Product Designation (FDA), Emergency (compassionate) Cost Recovery Sales Authorization (FDA) and "promising" clinical outcome recognition based on the evaluation of certain summary clinical reports (AHRQ, Agency Health Research Quality). Ampligen represents the first drug in the class of RNA (nucleic acid) molecules to apply for NDA review.

On July 7, 2008, the FDA accepted for review our NDA for Ampligen(R) to treat CFS, originally submitted in October 2007. We are seeking marketing approval for the first-ever treatment for CFS. At present, only supportive, symptom-based care is available for CFS patients. The NDA for Ampligen(R), whose chemical designation is poly I : poly C12U, is also the first ever accepted for review by the FDA for systemic use of a toll-like receptor therapy to treat any condition. On February 18, 2009, we were notified by the FDA that the originally scheduled Prescription Drug User Fee Act ("PDUFA") date of February 25, 2009 has been extended to May 25, 2009. For more information on our NDA, please see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations; Results of Operations; Year ended December 31, 2007 versus December 31, 2008; Research and Development Costs" and "Note 19: Subsequent Events" under Notes to Consolidated Financial Statements.

The Status of our initiative for Ampligen(R) as an adjuvant for preventative vaccine development includes the pre-clinical studies in seasonal and pandemic influenza for intranasal administration being conducted by Japan's National Institute for Infectious Diseases. A three year program targeting regulatory approval for pandemic flu and seasonal flu in Japan has been funded by the Japanese Ministry of Health. Parties to the research grant include Hemispherx, the NIID and BIKEN (operational arm of the non-profit Foundation for Microbial Disease of Osaka University). Our agreement with BIKEN is part of a three party agreement to develop an effective influenza vaccine for Japan and utilizes the resources of the National Institute of Infectious Disease of Japan. We intend to conduct human studies in the US and Australia to seek approval for seasonal and pandemic indications in the US and Europe for intranasal administration. A phase II study for intramuscular administration for seasonal flu was conducted in Australia through St. Vincent's Hospital Clinical Trials Centre. The clinical data from this trial is currently being analyzed and the

results are expected by mid-2009.

Based on the results of published, peer reviewed pre-clinical studies and clinical trials, we believe that Ampligen(R) may have broad-spectrum anti-viral and anti-cancer properties. Over 1,000 patients have participated in the Ampligen(R) clinical trials representing the administration of more than 90,000 doses of this drug.

Alferon N Injection(R) is the registered trademark for our injectable formulation of natural alpha interferon, which is approved by the FDA for the

treatment of genital warts. Alferon N Injection(R) is also in clinical development for treating West Nile Virus.

Commercial sales of Alferon N Injection(R) were halted in April 2008 as the current expiration date of our finished goods inventory expired in March 2008. The FDA has declined to respond to our requests for an extension of the expiration date, therefore we consider the request to be denied. Since our testing of the product indicates that it is not impaired and could be safely utilized, the finished goods inventory of 2,745 Alferon N Injection(R) 5ml vials may be used to produce approximately 11,000,000 sachets of Low Dose Oral Alferon (LDO) for future clinical trials.

Production of Alferon N injection(R) from our work-in-progress inventory, which has an approximate expiration date of 2012, has been put on hold at this time due to the resources needed to prepare our New Brunswick facility for the FDA preapproval inspection with respect to our Ampligen(R) NDA. Work on the Alferon N Injection(R) is expected to resume in mid-2009 under the condition that adequate funding is obtained, which means that we may not have any Alferon N Injection(R) product commercially available until 2010.

We own and operate a 43,000 sq. ft. FDA approved facility in New Brunswick, NJ primarily designed to produce Alferon N Injection(R). In 2006, we completed the installation of a polymer production line to produce Ampligen(R) raw materials on a more reliable and consistent basis.

We outsource certain components of our research and development, manufacturing, marketing and distribution while maintaining control over the entire process through our quality assurance group and our clinical monitoring group.

Our principal executive offices are located at One Penn Center, 1617 JFK Boulevard, Philadelphia, Pennsylvania 19103, and our telephone number is 215-988-0080.

AVAILABLE INFORMATION

We file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 electronically with the Securities and Exchange Commission, or SEC. The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is http://www.sec.gov.

You may obtain a free copy of our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and amendments to those reports on the day of filing with the SEC on our website on the World Wide Web at http://www.hemispherx.net or by contacting the Investor Relations

Department by calling (518) 398-6222 or sending an e-mail message to dwill@willstar.net.

OUR PRODUCTS

Our primary products consist of our experimental compound, Ampligen(R), our FDA approved natural interferon product, Alferon N Injection(R) and Alferon(R) LDO (low dose oral) our experimental liquid natural interferon for oral administration.

Ampligen(R)

Nucleic acid compounds represent a potential new class of pharmaceutical products that are designed to act at the molecular level for treatment of human diseases. There are two forms of nucleic acids, DNA and RNA. DNA is a group of naturally occurring molecules found in chromosomes, the cell's genetic machinery. RNA is a group of naturally occurring informational molecules which orchestrate a cell's behavior which regulates the action of groups of cells, including the cells which compromise the body's immune system. RNA directs the production of proteins and regulates certain cell activities including the activation of an otherwise dormant cellular defense against viruses and tumors. Our drug technology utilizes specifically-configured RNA. Our double-stranded RNA drug product, trademarked Ampligen(R), an experimental, unapproved drug, which is administered intravenously, is in human clinical development for various therapeutically oriented studies, including treatment for Myalgic Encephalomyelitis / Chronic Fatigue Syndrome ("ME/CFS"), HIV, renal cell carcinoma and malignant melanoma.

Clinical trials already conducted by us include Ampligen(R) treatments of ME/CFS, Hepatitis B, HIV and cancer patients with renal cell carcinoma and malignant melanoma. Certain of these will require additional clinical trials to support regulatory approval.

The FDA has approved the use of Ampligen(R) in treating ME/CFS on an emergency basis (i.e. those with immediate life threatening illnesses). This is known as a treatment IND, or Treatment Investigational New Drug. Furthermore, the FDA has granted Hemispherx Orphan Drug Status in the United States. Orphan drugs get seven years of market exclusivity upon FDA approval.

Alferon N Injection(R)

Interferons are a group of proteins produced and secreted by cells to combat diseases. Researchers have identified four major classes of human interferon: alpha, beta, gamma and omega. The Alferon N Injection(R) product contains a multi-species form of alpha interferon. The worldwide market for injectable alpha interferon-based products has experienced rapid growth and various alpha interferon injectable products are approved for many major medical uses worldwide. Alpha interferons are manufactured commercially in three ways: by genetic engineering, by cell culture, and from human white blood cells. All three of these types of alpha interferon are or were approved for commercial sale in the U.S. Our natural alpha interferon is produced from human white blood cells.

The potential advantages of natural alpha interferon over recombinant (synthetic) interferon produced and marketed by other pharmaceutical firms may be based upon their respective molecular compositions. Natural alpha interferon is composed of a family of proteins containing many molecular species of interferon. In contrast, commercial recombinant alpha interferon each contain

only a single species. Researchers have reported that the various species of interferons may have differing antiviral activity depending upon the type of virus. Natural alpha interferon presents a broad complement of species, which we believe may account for its higher activity in laboratory studies. Natural alpha interferon is also glycosylated (partially covered with sugar molecules). Such glycosylation is not present on the currently U.S. marketed recombinant alpha interferons. We believe that the absence of glycosylation may be, in part, responsible for the production of interferon-neutralizing antibodies seen in patients treated with recombinant alpha interferon. Although cell culture-derived interferon is also composed of multiple glycosylated alpha interferon species, the types and relative quantity of these species are different from our natural alpha interferon.

The FDA approved Alferon N Injection(R) in 1989 for the intralesional (within lesions) treatment of refractory (resistant to other treatment) or recurring external genital warts in patients 18 years of age or older. Certain types of human papillomaviruses ("HPV") cause genital warts, a sexually transmitted disease ("STD"). A published report estimates that approximately eight million new and recurrent causes of genital warts occur annually in the United States alone.

Alferon N Injection(R) [Interferon alfa-n3] (human leukocyte derived)] is a highly purified, natural-source, glycosylated, multi-species alpha interferon product. There are essentially no antibodies observed against natural interferon to date and the product has a relatively low side-effect profile. Alferon(R) is the only natural-source, multi-species alpha interferon currently sold in the U.S.

The recombinant DNA derived alpha interferon are now reported to have decreased effectiveness after one year, probably due to antibody formation and other severe toxicities. These detrimental effects have not been reported with the use of Alferon N Injection(R) which could allow this product to assume a much larger market share.

It is our belief that the use of Alferon(R) N in combination with Ampligen(R) has the potential to increase the positive therapeutic responses in chronic life threatening viral diseases. We have suspended certain preclinical trials for various viral disorders at this time due to funding considerations and increased resource requirements of other projects.

Alferon(R) Low Dose Oral (LDO)

Alferon(R) LDO is an experimental low-dose, oral liquid formulation of Natural Alpha Interferon and like Alferon N Injection(R) should not cause antibody formation, which is a problem with recombinant interferon. It is an experimental immunotherapeutic believed to work by stimulating an immune cascade response in the cells of the mouth and throat, enabling it to bolster systemic immune response through the entire body by absorption through the oral mucosa. Oral interferon would be much more economically feasible for patients and logistically manageable in development programs in third-world countries primarily affected by HIV and other emerging viruses (SARS, Ebola, bird flu, etc.). Oral administration of Alferon(R) N, with its affordability, low toxicity, no production of antibodies, and broad range of potential bio activity, could be a breakthrough treatment for viral diseases.

We have conducted clinical trials as part of an evaluation of the experimental bio-therapeutic Alferon(R) LDO (Low Dose Oral Interferon Alfa-n3 (Human Leukocyte Derived)) as a potential new experimental therapy for Avian Flu and other lethal viral diseases, which have high acute death rates. Clinical trials in human volunteers (conducted in both the US at Drexel University,

Philadelphia and in Hong Kong at the Princess Margaret Hospital) were designed

to determine whether Alferon(R) N, delivered in a new, experimental oral drug delivery format, can resuscitate the broad-spectrum antiviral and immunostimulatory genes. These human genes are shut down by acute lethal viral infections such as HIV, avian flu and smallpox. The results of this study are being evaluated.

Oragens

We acquired a series of patents on Oragens, potentially a set of oral broad spectrum antivirals and immunological enhancers, through a licensing agreement with Temple University in Philadelphia, PA. We were granted an exclusive worldwide license from Temple for the Oragens products. These compounds have been evaluated in various academic laboratories for application to chronic viral and immunological disorders.

The 2', 5' oligoadenylate synthetase/RNase L system is an important and widely distributed pathway for the inhibition of viral replication and tumor growth. The 2', 5' oligoadenylate synthetase, up activation by double-stranded RNA, synthesizes 2', 5' oligoadenylates (2-5A) from ATP. These bioactive 2-5As directly activate RNase L, which degrades viral and cellular RNAs resulting in the inhibition of protein synthesis.

The bioactive 2-5A molecules can be degraded by various hydrolytic enzymes, resulting in a short half life. Analogues of these bioactive 2-5As, termed Oragen RNA compounds, have been produced to increase stability and maintain or increase biological activity without demonstrable toxicity. Additional pre-clinical tests will need to be conducted prior to pursuing clinical trials.

PATENTS

We have over 50 patents worldwide with approximately 30 additional pending patent applications pending comprising our intellectual property. In 2006, we obtained the global patent rights for a compound that enhances DNA vaccination by the efficient intracellular delivery of immunogenic DNA (i.e.- DNA that can produce antigenic proteins that simulate an acute viral infection with a resultant humoral and cell-mediated immune response). Please see "Note 5: Patents, Trademark Rights and Other Intangibles" under Notes To Consolidated Financial Statements for more information on these patents.

We continually review our patents rights to determine whether they have continuing value. Such review includes an analysis of the patent's ultimate revenue and profitability potential. In addition, management's review addresses whether each patent continues to fit into our strategic business plans for Ampligen(R), Alferon(R) N and other intellectual property.

Our experimental compounds, which have yet to be determined "safe and effective" by regulatory authorities, are accordingly only available legally in certain authorized trials and tests; in vitro (outside the body) tests are also not necessarily indicative of any evidence of clinical benefits or advantages. But the current focus of Hemispherx is on Ampligen(R) as a treatment for ME/CFS.

The main U.S. ME/CFS treatment patent (#6130206) expires October 10, 2017. Our main patents covering HIV treatment (#4820696, #5063209, and #5091374) expired on April 11, 2006, November 5, 2008, and February 25, 2009, respectively; Hepatitis treatment coverage is conveyed by U.S. patent #5593973 which expires on January 14, 2014. The U.S. Ampligen(R) Trademark (#1,515,099)

expired on December 6, 2008 and we are in the renewal process for an additional 10 years of patent protection. The FDA has granted us "orphan drug status" for our nucleic acid-derived therapeutics for ME/CFS, HIV/AIDS, and renal cell carcinoma and malignant melanoma. Orphan drug status grants us protection

against competition for a period of seven years following FDA approval, as well as certain federal tax incentives, and other regulatory benefits. The HIV/AIDS indication will be covered under the marketing protection provided by the orphan drug designation for using Ampligen(R) to treat HIV/AIDS.

The U.S. Alferon(R) Patents expire February 10, 2012 (5,503,828 and 5,676,942) and December 22, 2017 (5,989,441).

RESEARCH AND DEVELOPMENT ("R&D")

Our focus is on developing drugs for use in treating viral and immune based chronic disorders and diseases such as ME/CFS, HIV, HPV, SARS and West Nile Virus. Due to limited capital resources, our current R&D projects are only targeting treatment therapies for ME/CFS and other viral diseases, i.e.; Avian/Seasonal Influenza.

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome ("ME/CFS")

Chronic Fatigue Syndrome ("CFS"), also known as Chronic Immune Dysfunction Syndrome ("CFIDS") and, myalgic encephalomyelitis ("ME") is a serious and debilitating chronic illness and a major public health problem. Long misunderstood, under-recognized, and under-diagnosed, ME/CFS is now recognized by both the government and private sector as a major health problem, including the National Institutes of Health, U.S. Centers for Disease Control and Prevention ("CDC"), FDA and Social Security Administration, recognizes ME/CFS as one of the most common chronic illnesses of our time. The CDC listed ME/CFS as a priority disease, causing severe health and financial problems for the patients, their family, and the community. ME/CFS is endemic in the population, but occasionally seen in clusters suggesting an infectious basis. A variety of immunological, endocrine, autonomic nervous system, and metabolic abnormalities have been documented.

CDC Director Dr. Julie Gerberding has stated that "The CDC considers Chronic Fatigue Syndrome to be a significant public health concern and we are committed to research that will lead to earlier diagnosis and better treatment of the illness." A variety of studies by the CDC and others have shown that between 1 and 4 million Americans suffer from CFS. While those with the disease are seriously impaired and at least a quarter are unemployed or on disability because of CFS, only about half have consulted a physician for their illness. Equally important, about 40% of people in the general population who report symptoms of ME/CFS have a serious, treatable, previously unrecognized medical or psychiatric condition (such as diabetes, thyroid disease, substance abuse). ME/CFS is a serious illness and poses a dilemma for patients, their families and health care providers.

The CDC has launched a national public education and awareness campaign on CFS. The campaign, called "Get Informed. Get Diagnosed. Get Help." is designed to increase awareness among clinicians and the public because 80 percent of Americans afflicted with CFS illness may not know they have it. The campaign provides the latest information regarding the diagnosis and treatment of CFS along with national print and broadcast advertising designed to raise awareness of the disease among patients and clinicians. A CDC sponsored website

at www.cdc.gov/cfs provides easy to understand, downloadable educational tools for patients, their families and health care professionals.

While ME/CFS strikes people of all age, racial, ethnic, and socioeconomic groups, it is most prevalent amongst women. Research has shown that ME/CFS is about three times as common in women as men, a rate similar to that of many autoimmune diseases, such as multiple sclerosis and lupus. To put this into perspective, ME/CFS is over four times more common than HIV infection in women, and the rate of ME/CFS in women is considerably higher than a woman's

lifetime risk of getting lung cancer as published by the CFIDS Association of America.

Many severe ME/CFS patients become completely disabled or totally bedridden and are afflicted with severe pain and mental confusion even at rest. ME/CFS is characterized by incapacitating fatigue with profound exhaustion and extremely poor stamina, sleep difficulties and problems with concentration and short-term memory. It is also accompanied by flu-like symptoms, pain in the joints and muscles, tender lymph nodes, sore throat and new headaches. A distinctive characteristic of the illness is a worsening of symptoms following physical or mental exertion which do not subside with rest.

Because no cause for ME/CFS has been identified, current treatment programs are directed at relieving symptoms, with the goal of the patient regaining some level of function and well-being. Diagnosis of ME/CFS is a time-consuming and challenging process for which there is no diagnostic test or biomarker to clearly identify the disorder. Diagnosis is primarily arrived at by taking a patient's medical history, completing a physical exam and lab tests to rule out other conditions excluding other illnesses with similar symptoms and comparing a patient's symptoms with the case definition. Overlapping symptoms can occur with several diseases, such as fibromyalgia, Gulf War Illnesses and multiple chemical sensitivities. Many diseases have similar symptoms including Lupus and Lyme disease which may closely mimic ME/CFS that they need to be considered when making a diagnosis to rule them out. If there are no abnormal test results or other physical ailments identified, clinicians can use standardized tests to quantify the level of fatigue and evaluate symptoms. Diagnosis can be complicated by the fact that the symptoms and severity of CFS vary considerably from patient to patient.

The case definition for ME/CFS criteria calls for certain symptoms to be present along with fatigue that interferes with physical, mental, social, and educational activities. Both the fatigue and symptoms must have occurred for (at least) a six month period. People with ME/CFS may experience many more than the symptoms named in the case definition, so knowledgeable physicians will take this fact into consideration when making a diagnosis (after other possible reasons for symptoms have been ruled out).

The leading model of ME/CFS pathogenesis is thought to be rooted in abnormalities in the immune system and brain (central nervous system), both of which affects and alters the function of the other. Because some cases of chronic fatigue begin with a flu-like infection, several viruses have been studied as possible causes because all are relatively common in the general population, including Human Herpesvirus ("HHV") 6 and 7, Retroviruses, Epstein-Barr Virus, Enteroviruses, as well as, Mycoplasmas, etc. Whilst, the etiology is likely to be caused by a collection of factors, including viral, hormonal, stress, and other triggers for the illness in genetically, environmentally or otherwise susceptible individuals and continues to be a subject of discussion.

Most ME/CFS patients are treated symptomatically with traditional treatments geared toward treating symptoms of the disease, such as improving quality of sleep, reducing pain and treatment of depression. Clinically, a number of different therapeutic approaches have been pursued, but with no significant clinical success.

Other Viral Diseases

We are actively engaged in broad-based experimental studies assessing the efficacy of our products, Ampligen(R), Alferon N Injection(R) and Alferon(R) LDO against influenza viruses as an adjuvant and/or single agent antiviral with the National Institute of Infectious Disease in Tokyo, St. Vincent's Hospital Clinical Trial Centre in Australia and various research affiliates of the

National Institutes of Health in the United States.

In September 2007, Japan's National Institute of Infectious Disease ("JNIID") initiated research on the co-administration of JNIID's HIV-1 vaccine with our experimental TLR3 agonist, Ampligen(R). Activation of TLR3 by Ampligen(R) triggers a host defense innate immune response in the cell. This research is the result of earlier studies suggesting a potential role for Ampligen(R) in boosting responses to certain vaccines designed to combat avian influenza (Bird Flu) as well as seasonal influenza viruses. The objective of this research is to determine if Ampligen(R) can overcome the historical problem which has handicapped HIV/AIDS vaccine development, namely marginal immune response which undermines the potential of long-lasting protection. Ampligen(R) will be combined with HIV/AIDS recombinant protein and administered via an intranasal route.

In 2007 JNIID published in two peer reviewed journals, the results of their studies to evaluate the ability of current seasonal influenza vaccine to confer cross-protection against highly pathogenic H5N1 influenza (Bird Flu) virus in mice. These studies indicate that, as a vaccine enhancer co-administered with their seasonal trivalent influenza vaccine, Ampligen(R) helps induce a protective effect against H5N1 influenza viruses. As such, Ampligen(R) as a toll-like receptor 3 agonist may aid in overcoming the problems protecting against mutated strains of the H5N1 virus and of limited supplies of H5N1 virus vaccines. Additional studies to support this conclusion are being planned.

In April 2007, Japan's Ministry of Health, Labor and Welfare (MHLW) issued authorization to its National Institute of Infectious Diseases approving their budget to advance studies indicating that an H5N1 influenza vaccine co-administered intranasally with Hemispherx's experimental therapeutic, Ampligen(R), protected against mutated strains of the virus and, further that, the seasonal trivalent influenza vaccine co-administered intranasally with Ampligen(R) maintained efficacy even when challenged with the H5N1 influenza virus.

In June 2007, we initiated a clinical trial in Australia using Ampligen(R) in combination with seasonal flu vaccine. This open-label study (Phase IIa) utilizing Ampligen(R) (Poly I: Poly C12U) as a potential immune-enhancer was conducted in Australia with thirty-eight subjects age 60 or greater with the standard trivalent seasonal influenza vaccines. Ampligen(R) was administered subcutaneously. Elderly subjects typically have reduced immune responses relative to younger populations. The combinational treatment was generally well-tolerated. Serologic studies to evaluate the magnitude and spectrum of immune response are pending and are expected by mid-2009; however, only certain labs are qualified to conduct these tests and during the course of
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the clinical testing, one of these testing labs changed ownership. We are in the process of determining that the methodology remained validated and consistent with the pilot results obtained about a year earlier with a smaller group consisting of the first 8 enrolled subjects.

The CDC reports that in 2007 the number of mosquito-borne West Nile Virus ("WNV") infections in the United States were "up sharply" over the same period in 2006. This increased infection rate has accelerated the enrollment of patients in the Phase IIb clinical trial using Alferon(R) N to treat WNV patients. In lab studies, Alferon(R) N, a natural cocktail of eight alpha-interferons, shows synergistic effects (up to 100 fold over recombinant interferons) against pathogens such as WNV. The Phase IIb clinical trial is a double-blinded, randomized, multi-center program under the direction of Cornell University and Weill Cornell Medical College/New York Hospital.

Our direct Research and Development cost was $5,800,000 in 2008,

$10,444,000 in 2007 and $10,127,000 in 2006. Most of these expenditures relate to the development of our experimental drug, Ampligen(R). The costs in 2006 and 2007 reflect the costs of producing Ampligen(R) raw materials (polymers) and Ampligen(R) doses for use in stability and validation testing, including the costs of preparing the NDA for filing with the FDA.

MANUFACTURING

We have a Supply Agreement with Hollister-Stier Laboratories LLC ("Hollister-Stier") of Spokane, Washington related to the manufacture of Ampligen(R) for a five year term ending in 2010. Pursuant to the agreement, we supply the key raw materials and Hollister-Stier formulates and bottles Ampligen(R). Hollister-Stier has completed five (5) pilot manufacturing runs of Ampligen(R) for stability testing with one additional manufacturing run which was completed mid-March 2007. The first three pilot runs were completed in January 2006 utilizing polymer/raw material from Ribotech (our previous supplier of raw material). A six month accelerated stability data on these three lots support a two year expiration period to 2011. Having successfully completed these manufacturing runs, the scale up of Ampligen(R) manufacturing to commercial batch size and the validation of the manufacturing at Hollister-Stier was initiated. We are currently using these three process validation lots in stability studies to monitor and confirm the product quality and stability.

Alferon N Injection(R), the purified drug concentrate utilized in the formulation of Alferon N Injection(R), was manufactured in our New Brunswick, New Jersey facility and was formulated and packaged at a production facility formerly owned and operated by Abbott Laboratories located in Kansas. Abbott Laboratories sold the facility to Hospira. Hospira ceased the labeling and packaging of Alferon N Injection(R) as they sought larger production runs for cost efficiency purposes. On February 8, 2006, we executed a Manufacturing and Safety Agreement with Hyaluron, Inc. ("Hyaluron") of Burlington, Massachusetts, for the formulation, packaging and labeling of Alferon N Injection(R). Pursuant to the Agreement, we will supply raw materials in sufficient quantity and provide any pertinent information to the project. Hyaluron is in the process of preparing their facility to produce Alferon N Injection(R). At this time we are in the process of scheduling additional production runs in 2010.

MARKETING/DISTRIBUTION

Our marketing strategy for Ampligen(R) reflects the differing health care systems around the world, and the different marketing and distribution systems that are used to supply pharmaceutical products to those systems. In the
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U.S., we expect that, subject to receipt of regulatory approval, Ampligen(R) may be utilized in four medical arenas: physicians' offices, clinics, hospitals and the home treatment setting. We are in the process of developing pre-launch and launch driven marketing plans focusing on those audience development, medical support and payor reimbursement initiatives which will facilitate product acceptance and utilization at the time of regulatory approval. Similarly, we are developing distribution scenarios for the Specialty Pharmacy/Infusion channel which will insure market access, offer 3PL (third party logistics) capabilities and provide the requisite risk management control mechanisms. It is our intent to utilize third party service providers to execute elements of both the marketing/sales and distribution plans. We currently plan to utilize a small group of Managed Market account managers to introduce the product to payor, employer and government account audiences. We believe that this approach will establish a market presence and facilitate the generation of revenue without incurring the substantial costs associated with a traditional sales force. Furthermore, management believes that the approach will enable us to retain many options for future marketing strategies.

For example, our commercialization strategy for Ampligen(R)-CFS may

include licensing/co-marketing agreements utilizing the resources and capacities of a strategic partner(s). We are currently seeking worldwide marketing partner(s), with the goal of having a relationship in place before approval is obtained. In parallel to partnering discussions, appropriate pre-marketing activities will be undertaken. We intend to control manufacturing of Ampligen on a world-wide basis.

In 1998, we entered into a strategic alliance with Accredo to develop certain marketing and distribution capacities for Ampligen(R) in the United States. Accredo, a division of MEDCO, is one of the nation's largest Specialty Pharmacy providers. Pursuant to the agreement, Accredo assumed certain responsibilities for distribution of Ampligen(R) for which they received a fee. Through this arrangement, we may mitigate the necessity of incurring certain up-front costs. Accredo has also worked with us in connection with the Amp 511 ME/CFS cost recovery treatment program, Amp 516 ME/CFS Phase III clinical trial and the Amp 719 (combining Ampligen(R) with other antiviral drugs in HIV-salvage therapy and Amp 720 HIV Phase IIb clinical trials now under way). There can be no assurances that this alliance will develop a significant commercial position in any of its targeted chronic disease markets. The agreement had an initial one year term from February 9, 1998 with successive additional one year terms unless either party notifies the other not less than 180 days prior to the anniversary date of its intent to terminate the agreement. Also, the agreement may be terminated for uncured defaults, or bankruptcy, or insolvency of either party and will automatically terminate upon our receiving an NDA for Ampligen(R) from the FDA, at which time, a new agreement will need to be negotiated with Accredo or another major drug distributor. This agreement offers the potential to provide some marketing and distribution capacity in the United States. There has been no communication or activity under this agreement for the past few years.

In 2007, we had executed a marketing strategy for Alferon N Injection(R) by relaunching the product via a collaborative marketing initiative between Hemispherx and Armada Healthcare, a Specialty Pharmacy network encompassing specialty pharmacists, pharmacies, distributors and targeted physician specialists. This effort was intended to direct our efforts in the most appropriate and productive market fully exposing our product in the indicated market. This initiative had a positive impact on Alferon(R) revenues in 2007 by focusing on direct, non-personal selling efforts to targeted physician audiences. It was our intent to promote Alferon to those dermatologists, OB GYNs and Family practice/IMs who are involved in the

treatment of patients with refractory or recurring external genital warts and who currently utilize both injectable interferons as well as topical therapeutic agents. This marketing initiative has been put on hold due to lack of commercially marketable product. We expect to reactivate Alferon(R) N production and the marketing program in 2010.

COMPETITION

RNA based products and toll-like receptors (TLRs) have demonstrated great promise in pre-clinical and limited clinical applications resulting in active research and development by large pharmaceutical companies and emerging Biotech firms. As such, our potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have.

These companies and their competing products may be more effective and less costly than our products. In addition, conventional drug therapy, surgery

and other more familiar treatments will offer competition to our products. Furthermore, our competitors have significantly greater experience than we do in pre-clinical testing and human clinical trials of pharmaceutical products and in obtaining FDA, EMEA Health Protection Branch ("HPB") and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA, EMEA and HPB product approvals more rapidly than us. If any of our products receive regulatory approvals and we commence commercial sales of our products, we will also be competing with respect to manufacturing efficiency and marketing capabilities, areas in which we have no experience. Our competitors may possess or obtain patent protection or other intellectual property rights that prevent, limit or otherwise adversely affect our ability to develop or exploit our products.

The major pharmaceutical competitors with biotech capabilities/vaccine franchises include Pfizer, GSK, Wyeth, Merck, Novartis, Gilead Pharmaceutical, and Schering-Plough Corp. Biotech competitors include AVANT Immunotherapeutics, AVI Biopharma and GENTA. When we recommence sales of Alferon N Injection(R), it will again compete with a product produced by Schering for treating genital warts. 3M Pharmaceutical also markets its immune response modifier product, Aldera, for the treatment of genital and perianal warts. We believe the approval and marketing of this product is the main reason that past sales of Alferon N Injection(R) have not met our expectations since acquisition. In November 2006, the botanical drug, Veregen (marketed by Bradley Pharmaceuticals) was also approved for the topical treatment of genital and perianal warts. In addition, because certain competitive products are not dependent on a source of human blood cells, such products may be able to be produced in greater volume and at a lower cost than Alferon N Injection(R). Our wholesale price on a per unit basis of Alferon N Injection(R) is higher than that of the competitive recombinant alpha and beta interferon products.

GOVERNMENT REGULATION

Regulation by governmental authorities in the U.S. and foreign countries is and will be a significant factor in the manufacture and marketing of Alferon(R) N products and our ongoing research and product development activities. Ampligen(R) and the products developed from the ongoing research and product development activities will require regulatory clearances prior to commercialization. In particular, new drug products for humans are subject to

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rigorous preclinical and clinical testing as a condition for clearance by the FDA and by similar authorities in foreign countries. The lengthy process of seeking these approvals, and the ongoing process of compliance with applicable statutes and regulations, has, and will continue to require the expenditure of substantial resources. Any failure by us or our collaborators or licensees to obtain, or any delay in obtaining, regulatory approvals could materially adversely affect the marketing of any products developed by us and our ability to receive product or royalty revenue. We have received orphan drug designation for certain therapeutic indications, which might, under certain conditions, accelerate the process of drug commercialization. Alferon N Injection(R) is only approved for use in intra-lesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of Alferon N Injection(R) for other applications requires regulatory approval.

We are subject to various federal, state and local laws, regulations and recommendations relating to such matters as safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use of and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work. The laboratory and production facility in New Brunswick, New Jersey is approved for the manufacture of Alferon N Injection(R) and we believe it is in substantial compliance with all material regulations. However, we cannot give assurances that facilities owned and operated by third parties that

are utilized in the manufacture of our products, are in substantial compliance, or if presently in substantial compliance, will remain so.

RESEARCH, CONSULTING, LICENSING AND SUPPLY AGREEMENTS

Please see "Note 10: Research, Consulting and Supply Agreements" under Notes to Consolidated Financial Statements.

HUMAN RESOURCES

As of March 3, 2009, we had 46 personnel consisting of 32 full time employees and 14 regulatory/research medical personnel on a part-time basis. Part time personnel are paid on a per diem or monthly basis. 27 personnel are engaged in our research, development, clinical, and manufacturing effort. 19 of our personnel perform regulatory, general administration, data processing, including bio-statistics, financial and investor relations functions. We have no union employees and we believe our relationship with our employees is good.

While we have been successful in attracting skilled and experienced scientific personnel, there can be no assurance that we will be able to attract or retain the necessary qualified employees and/or consultants in the future.

SCIENTIFIC ADVISORY BOARD

Our Scientific Advisory Board presently consists of two individuals who we believe have particular scientific and medical expertise in Virology, Cancer, Immunology, Biochemistry and related fields. Dr. James Rahal of New York Hospital Queens and Prof. Luc Montagnier from the Pasteur/World AIDS Research & Prevention advise us about current and long term scientific planning including research and development. This Board was originally made up of four medical scientists of which one resigned due to conflict of interest and one resigned for personal reasons. The Scientific Advisory Board conducts periodic meetings as needed by the clinical studies in progress by us. No Scientific Advisory Board meetings were held in 2008 primarily due to fewer active scientific

projects. However, individual Scientific Advisory Board Members sometimes consult with and meet informally with our employees. Members of the Scientific Advisory are employed by others and may have commitments to and/or consulting agreements with other entities, including our potential competitors.

ITEM 1A. Risk Factors.

The following cautionary statements identify important factors that could cause our actual results to differ materially from those projected in the forward-looking statements made in this Form 10-K. Among the key factors that have a direct bearing on our results of operations are:

Risks Associated With Our Business

No assurance of successful product development.

Ampligen(R) and related products. The development of Ampligen(R) and our other related products is subject to a number of significant risks. Ampligen(R) may be found to be ineffective or to have adverse side effects, fail to receive necessary regulatory clearances, be difficult to manufacture on a commercial scale, be uneconomical to market or be precluded from commercialization by proprietary right of third parties. Our products are in various stages of clinical and pre-clinical development and, require further clinical studies and appropriate regulatory approval processes before any such products can be marketed. We do not know when, if ever, Ampligen(R) or our other products will be generally available for commercial sale for any indication.

Generally, only a small percentage of potential therapeutic products are eventually approved by the FDA for commercial sale. Please see the next risk factor.

Alferon N Injection(R). Although Alferon N Injection(R) is approved for marketing in the United States for the intra-lesional treatment of refractory or recurring external genital warts in patients 18 years of age or older, to date it has not been approved for other indications. We face many of the risks discussed above, with regard to developing this product for use to treat other ailments.

Our drug and related technologies are investigational and subject to regulatory approval. If we are unable to obtain regulatory approval, our operations will be significantly adversely affected.

All of our drugs and associated technologies, other than Alferon N Injection(R), are investigational and must receive prior regulatory approval by appropriate regulatory authorities for general use and are currently legally available only through clinical trials with specified disorders. At present, Alferon N Injection(R) is only approved for the intra-lesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of Alferon N Injection(R) for other indications will require regulatory approval.

Our products, including Ampligen(R), are subject to extensive regulation by numerous governmental authorities in the U.S. and other countries, including, but not limited to, the FDA in the U.S., the Health Protection Branch ("HPB") of Canada, and the Agency for the Evaluation of Medicinal Products ("EMEA") in Europe. Obtaining regulatory approvals is a rigorous and lengthy process and requires the expenditure of substantial resources. In order to obtain final regulatory approval of a new drug, we must demonstrate to the

satisfaction of the regulatory agency that the product is safe and effective for its intended uses and that we are capable of manufacturing the product to the applicable regulatory standards. We require regulatory approval in order to market Ampligen(R) or any other proposed product and receive product revenues or royalties. We cannot assure you that Ampligen(R) will ultimately be demonstrated to be safe or efficacious. In addition, while Ampligen(R) is authorized for use in clinical trials including a cost recovery program in the United States and Europe, we cannot assure you that additional clinical trial approvals will be authorized in the United States or in other countries, in a timely fashion or at all, or that we will complete these clinical trials.

We filed an NDA with the FDA for treatment of CFS on October 10, 2007. On December 5, 2007 we received an RTF letter from the FDA as our NDA filing was deemed "not substantially complete". We responded to the FDA's concerns by filing amendments to our NDA on April 25, 2008. These amendments should allow the FDA reviewers to better evaluate independently the statistical efficacy/safety conclusions of our NDA for the use of Ampligen(R) in treating CFS. On July 7, 2008 the FDA accepted our NDA filing for review. However, there are no assurances that upon review of the NDA that it will be approved by the FDA. On February 18, 2009, we were notified by the FDA that the originally scheduled Prescription Drug User Fee Act ("PDUFA") date of February 25, 2009 has been extended to May 25, 2009. For more information on our NDA, please see "Note 19: Subsequent Events" under Notes to Consolidated Financial Statements.

If Ampligen(R) or one of our other products does not receive regulatory approval in the U.S. or elsewhere, our operations most likely will be materially adversely affected.

We may continue to incur substantial losses and our future profitability is uncertain.

We began operations in 1966 and last reported net profit from 1985 through 1987. Since 1987, we have incurred substantial operating losses, as we pursued our clinical trial effort to get our experimental drug, Ampligen(R), approved. As of December 31, 2008, our accumulated deficit was approximately $197,409,000. We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

We may require additional financing which may not be available.

The development of our products will require the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of December 31, 2008, we had approximately $6,119,000 in cash and cash equivalents and short-term investments. Given the harsh economic conditions, we have reviewed every aspect of our operations for cost and spending reductions to assure the long term survival of our Company while maintaining the resources necessary to achieve our primary objectives of obtaining NDA approval of Ampligen(R) and securing a strategic partner (see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources"). Based on these actions, we
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anticipate, but cannot assure, that these funds will be sufficient to meet our operating cash requirements for the next 16 months.

We have in place two potential sources of financing: 1) a Common Stock Purchase Agreement (the "Purchase Agreement") with Fusion Capital Fund II, LLC ("Fusion") pursuant to which we have the right to sell shares of our Common Stock to Fusion (see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources; Equity Financing); and 2) a Standby Financing Agreement with certain of our executives, directors and strategic consultants (see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources; Standby Financing Agreement"). However, Fusion cannot purchase any shares of our common stock pursuant to the Purchase Agreement if the price of our common stock has three trading days with an average value below $0.40 over the prior twelve trading days. For the past few months, with limited exceptions, the price of our common stock has been below $0.40, thereby adversely affecting our ability to exercise the Fusion financing.

Assuming no material financing from the sale of securities to Fusion, financing under the Standby Financing Agreement is not sufficient and if we are unable to commercialize and sell Ampligen(R) and/or increase sales of Alferon N Injection(R) or our other products, we will need to secure other sources of funding through additional equity or debt financing or from other sources in order to satisfy our working capital needs and to complete the necessary clinical trials and the regulatory approval processes including the commercializing of Ampligen(R) products. In this regard we previously registered $50,000,000 worth of our securities in a universal shelf registration statement, none of which has been designated or issued. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock. There can be no assurances that we will raise adequate funds which may have a material adverse effect on our ability to develop our products or continue our operations.

Our Alferon N Injection(R) Commercial Sales have halted due to lack of finished goods inventory.

Our finished goods inventory of Alferon N Injection(R) reached it's expiration date in March 2008. As a result, we have no product to sell at this time. The FDA has declined to respond to our requests for an extension of the expiration date, therefore we consider the request to be denied. Since our testing of the product indicates that it is not impaired and could be safely utilized, the finished goods inventory of 2,745 Alferon N Injection(R) 5ml vials may be used to produce approximately 11,000,000 sachets of Low Dose Oral Alferon (LDO) for future clinical trials.

Production of Alferon N Injection(R) from our work-in-progress inventory, which has an approximate expiration date of 2012, has been put on hold at this time due to the resources needed to prepare our New Brunswick facility for the FDA preapproval inspection with respect to our Ampligen(R) NDA. Work on the Alferon N Injection(R) is expected to resume in mid-2009 under the condition that adequate funding is obtained, which means that we may not have any Alferon N Injection(R) product commercially available until 2010.

In 2007, we averaged Alferon N Injection(R) sales of approximately $77,000 per month. However with no FDA approval to extend the expiration date of our finished good inventory, we will no longer receive these monthly revenues.
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In addition, if there is a significant absence of the product from the market place, no assurance can be given that sales will return to prior levels.

Although preliminary in vitro testing indicates that Ampligen(R) enhances the effectiveness of different drug combinations on avian influenza, preliminary testing in the laboratory is not necessarily predictive of successful results in clinical testing or human treatment.

Ampligen(R) continues to undergo pre-clinical testing for possible treatment of avian flu. Although preliminary in vitro testing indicates that Ampligen(R) enhances the effectiveness of different drug combinations on avian flu, preliminary testing in the laboratory is not necessarily predictive of successful results in clinical testing or human treatment. No assurance can be given that similar results will be observed in clinical trials. Use of Ampligen(R) in the treatment of avian flu requires prior regulatory approval. Only the FDA can determine whether a drug is safe, effective or promising for treating a specific application. As discussed in the prior risk factor, obtaining regulatory approvals is a rigorous and lengthy process.

In addition, Ampligen(R) is currently being tested on strains of avian influenza virus. There are a number of strains and strains mutate. No assurance can be given that Ampligen(R) will be effective on any strains that might infect humans.

We may not be profitable unless we can protect our patents and/or receive approval for additional pending patents.

We need to preserve and acquire enforceable patents covering the use of Ampligen(R) for a particular disease in order to obtain exclusive rights for the commercial sale of Ampligen(R) for such disease. We obtained all rights to Alferon N Injection(R), and we plan to preserve and acquire enforceable patents covering its use for existing and potentially new diseases. Our success depends, in large part, on our ability to preserve and obtain patent protection for our products and to obtain and preserve our trade secrets and expertise. Certain of our know-how and technology is not patentable, particularly the procedures for the manufacture of our experimental drug, Ampligen(R), which is carried out according to standard operating procedure manuals. We also have been issued patents on the use of Ampligen(R) in combination with certain other drugs for

the treatment of chronic Hepatitis B virus, chronic Hepatitis C virus, and a patent which affords protection on the use of Ampligen(R) in patients with Chronic Fatigue Syndrome. We have not yet been issued any patents in the United States for the use of Ampligen(R) as a sole treatment for any of the cancers, which we have sought to target. With regard to Alferon N Injection(R), we have acquired from ISI its patents for natural alpha interferon produced from human peripheral blood leukocytes and its production process and we have filed a patent application for the use of Alferon(R) LDO in treating viral diseases including avian influenza. We cannot assure that our competitors will not seek and obtain patents regarding the use of similar products in combination with various other agents, for a particular target indication prior to our doing such. If we cannot protect our patents covering the use of our products for a particular disease, or obtain additional patents, we may not be able to successfully market our products.

The patent position of biotechnology and pharmaceutical firms is highly uncertain and involves complex legal and factual questions.

To date, no consistent policy has emerged regarding the breadth of protection afforded by pharmaceutical and biotechnology patents. There can be no
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assurance that new patent applications relating to our products or technology will result in patents being issued or that, if issued, such patents will afford meaningful protection against competitors with similar technology. It is generally anticipated that there may be significant litigation in the industry regarding patent and intellectual property rights. Such litigation could require substantial resources from us and we may not have the financial resources necessary to enforce the patent rights that we hold. No assurance can be made that our patents will provide competitive advantages for our products or will not be successfully challenged by competitors. No assurance can be given that patents do not exist or could not be filed which would have a materially adverse effect on our ability to develop or market our products or to obtain or maintain any competitive position that we may achieve with respect to our products. Our patents also may not prevent others from developing competitive products using related technology.

There can be no assurance that we will be able to obtain necessary licenses if we cannot enforce patent rights we may hold. In addition, the failure of third parties from whom we currently license certain proprietary information or from whom we may be required to obtain such licenses in the future, to adequately enforce their rights to such proprietary information, could adversely affect the value of such licenses to us.

If we cannot enforce the patent rights we currently hold we may be required to obtain licenses from others to develop, manufacture or market our products. There can be no assurance that we would be able to obtain any such licenses on commercially reasonable terms, if at all. We currently license certain proprietary information from third parties, some of which may have been developed with government grants under circumstances where the government maintained certain rights with respect to the proprietary information developed. No assurances can be given that such third parties will adequately enforce any rights they may have or that the rights, if any, retained by the government will not adversely affect the value of our license.

There is no guarantee that our trade secrets will not be disclosed or known by our competitors.

To protect our rights, we require certain employees and consultants to enter into confidentiality agreements with us. There can be no assurance that these agreements will not be breached, that we would have adequate and enforceable remedies for any breach, or that any trade secrets of ours will not otherwise become known or be independently developed by competitors.

We have limited marketing and sales capability. If we are unable to obtain additional distributors and our current and future distributors do not market our products successfully, we may not generate significant revenues or become profitable.

We have limited marketing and sales capability. We are dependent upon existing and, possibly future, marketing agreements and third party distribution agreements for our products in order to generate significant revenues and become profitable. As a result, any revenues received by us will be dependent in large part on the efforts of third parties, and there is no assurance that these efforts will be successful.

Our commercialization strategy for Ampligen(R)-CFS may include licensing/co-marketing agreements utilizing the resources and capacities of a strategic partner(s). We are currently seeking worldwide marketing partner(s),
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with the goal of having a relationship in place before approval is obtained. In parallel to partnering discussions, appropriate pre-marketing activities will be undertaken. We intend to control manufacturing of Ampligen on a world-wide basis.

We cannot assure that our U.S. or foreign marketing strategy will be successful or that we will be able to establish future marketing or third party distribution agreements on terms acceptable to us, or that the cost of establishing these arrangements will not exceed any product revenues. Our inability to establish viable marketing and sales capabilities would most likely have a materially adverse effect on us.

There are no long-term agreements with suppliers of required materials. If we are unable to obtain the required raw materials, we may be required to scale back our operations or stop manufacturing Alferon N Injection(R) and/or Ampligen(R).

A number of essential materials are used in the production of Alferon N Injection(R), including human white blood cells. We do not have long-term agreements for the supply of any of such materials. There can be no assurance we can enter into long-term supply agreements covering essential materials on commercially reasonable terms, if at all.

There are a limited number of manufacturers in the United States available to provide the polymers for use in manufacturing Ampligen(R). At present, we do not have any agreements with third parties for the supply of any of these polymers. We have established relevant manufacturing operations within our New Brunswick, New Jersey facility for the production of Ampligen(R) polymers from raw materials in order to obtain polymers on a more consistent manufacturing basis.

If we are unable to obtain or manufacture the required polymers, we may be required to scale back our operations or stop manufacturing. The costs and availability of products and materials we need for the production of Ampligen(R) and the commercial production of Alferon N Injection(R) and other products which we may commercially produce are subject to fluctuation depending on a variety of factors beyond our control, including competitive factors, changes in technology, and FDA and other governmental regulations and there can be no assurance that we will be able to obtain such products and materials on terms acceptable to us or at all.

There is no assurance that successful manufacture of a drug on a limited scale basis for investigational use will lead to a successful transition to commercial, large-scale production.

Small changes in methods of manufacturing, including commercial scale-up, may affect the chemical structure of Ampligen(R) and other RNA drugs, as well as their safety and efficacy, and can, among other things, require new clinical studies and affect orphan drug status, particularly, market exclusivity rights, if any, under the Orphan Drug Act. The transition from limited production of pre-clinical and clinical research quantities to production of commercial quantities of our products will involve distinct management and technical challenges and will require additional management and technical personnel and capital to the extent such manufacturing is not handled by third parties. There can be no assurance that our manufacturing will be successful or that any given product will be determined to be safe and effective, capable of being manufactured economically in commercial quantities or successfully marketed.

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We have limited manufacturing experience and capacity.

Ampligen(R) has been only produced in limited quantities for use in our clinical trials and we are dependent upon a third party supplier for substantially all of the production process. The failure to continue these arrangements or to achieve other such arrangements on satisfactory terms could have a material adverse affect on us. Also to be successful, our products must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. To the extent we are involved in the production process, our current facilities are not adequate for the production of our proposed products for large-scale commercialization, and we currently do not have adequate personnel to conduct commercial-scale manufacturing. We intend to utilize third-party facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. We will need to comply with regulatory requirements for such facilities, including those of the FDA pertaining to current Good Manufacturing Practices ("cGMP") regulations. There can be no assurance that such facilities can be used, built, or acquired on commercially acceptable terms, or that such facilities, if used, built, or acquired, will be adequate for our long-term needs. Please refer to the Risk Factor "Our Alferon N Injection(R) commercial sales have halted due to lack of finished goods inventory."

We may not be profitable unless we can produce Ampligen(R) or other products in commercial quantities at costs acceptable to us.

We have never produced Ampligen(R) or any other products in large commercial quantities. We must manufacture our products in compliance with regulatory requirements in large commercial quantities and at acceptable costs in order for us to be profitable. We intend to utilize third-party manufacturers and/or facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. If we cannot manufacture commercial quantities of Ampligen(R) or enter into third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. Also, each production lot of Alferon N Injection(R) is subject to FDA review and approval prior to releasing the lots to be sold. This review and approval process could take considerable time, which would delay our having product in inventory to sell.

Rapid technological change may render our products obsolete or non-competitive.

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Most of these entities have significantly greater research and development capabilities than us, as well as substantial marketing, financial and managerial resources, and represent significant competition for us. There can be no assurance that developments by others will not render our products or

technologies obsolete or noncompetitive or that we will be able to keep pace with technological developments.

Our products may be subject to substantial competition.

Ampligen(R). Competitors may be developing technologies that are, or in the future may be, the basis for competitive products. Some of these potential products may have an entirely different approach or means of accomplishing similar therapeutic effects to products being developed by us. These competing

products may be more effective and less costly than our products. In addition, conventional drug therapy, surgery and other more familiar treatments may offer competition to our products. Furthermore, many of our competitors have significantly greater experience than us in pre-clinical testing and human clinical trials of pharmaceutical products and in obtaining FDA, HPB and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA, HPB or other regulatory product approvals more rapidly than us. There are no drugs approved for commercial sale with respect to treating ME/CFS in the United States. The dominant competitors with drugs to treat disease indications in which we plan to address include Gilead Pharmaceutical, Pfizer, Bristol-Myers, Abbott Labs, GlaxoSmithKline, Merck and Schering-Plough Corp. These potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. Although we believe our principal advantage is the unique mechanism of action of Ampligen(R) on the immune system, we cannot assure that we will be able to compete.

ALFERON N Injection(R). Our competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. Alferon N Injection(R) currently competes with Schering's injectable recombinant alpha interferon product (INTRON(R) A) for the treatment of genital warts. 3M Pharmaceuticals also offer competition from its immune-response modifier, Aldara(R), a self-administered topical cream, for the treatment of external genital and perianal warts. In addition, Medigene has FDA approval for a self-administered ointment, VeregenTM, which is indicated for the topical treatment of external genital and perianal warts. Alferon N Injection(R) also competes with surgical, chemical, and other methods of treating genital warts. We cannot assess the impact products developed by our competitors, or advances in other methods of the treatment of genital warts, will have on the commercial viability of Alferon N Injection(R). If and when we obtain additional approvals of uses of this product, we expect to compete primarily on the basis of product performance. Our competitors have developed or may develop products (containing either alpha or beta interferon or other therapeutic compounds) or other treatment modalities for those uses. There can be no assurance that, if we are able to obtain regulatory approval of Alferon N Injection(R) for the treatment of new indications, we will be able to achieve any significant penetration into those markets. In addition, because certain competitive products are not dependent on a source of human blood cells, such products may be able to be produced in greater volume and at a lower cost than Alferon N Injection(R). Currently, our wholesale price on a per unit basis of Alferon N Injection(R) is higher than that of the competitive recombinant alpha and beta interferon products.

General. Other companies may succeed in developing products earlier than we do, obtaining approvals for such products from the FDA more rapidly than we do, or developing products that are more effective than those we may develop. While we will attempt to expand our technological capabilities in order to remain competitive, there can be no assurance that research and development by others or other medical advances will not render our technology or products

obsolete or non-competitive or result in treatments or cures superior to any therapy we develop.

Possible side effects from the use of Ampligen(R) or Alferon N Injection(R) could adversely affect potential revenues and physician/patient acceptability of our product.

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Ampligen(R). We believe that Ampligen(R) has been generally well tolerated with a low incidence of clinical toxicity, particularly given the severely debilitating or life threatening diseases that have been treated. A mild flushing reaction has been observed in approximately 15-20% of patients treated in our various studies. This reaction is occasionally accompanied by a rapid heart beat, a tightness of the chest, urticaria (swelling of the skin), anxiety, shortness of breath, subjective reports of "feeling hot", sweating and nausea. The reaction is usually infusion-rate related and can generally be controlled by reducing the rate of infusion. Other adverse side effects include liver enzyme level elevations, diarrhea, itching, asthma, low blood pressure, photophobia, rash, transient visual disturbances, slow or irregular heart rate, decreases in platelets and white blood cell counts, anemia, dizziness, confusion, elevation of kidney function tests, occasional temporary hair loss and various flu-like symptoms, including fever, chills, fatigue, muscular aches, joint pains, headaches, nausea and vomiting. These flu-like side effects typically subside within several months. One or more of the potential side effects might deter usage of Ampligen(R) in certain clinical situations and therefore, could adversely affect potential revenues and physician/patient acceptability of our product.

Alferon N Injection(R). At present, Alferon N Injection(R) is only approved for the intra-lesional (within the lesion) treatment of refractory or recurring external genital warts in adults. In clinical trials conducted for the treatment of genital warts with Alferon N Injection(R), patients did not experience serious side effects; however, there can be no assurance that unexpected or unacceptable side effects will not be found in the future for this use or other potential uses of Alferon N Injection(R) which could threaten or limit such product's usefulness.

We may be subject to product liability claims from the use of Ampligen(R), Alferon N Injection(R), or other of our products which could negatively affect our future operations. We have temporarily discontinued product liability insurance.

We face an inherent business risk of exposure to product liability claims in the event that the use of Ampligen(R) or other of our products results in adverse effects. This liability might result from claims made directly by patients, hospitals, clinics or other consumers, or by pharmaceutical companies or others manufacturing these products on our behalf. Our future operations may be negatively affected from the litigation costs, settlement expenses and lost product sales inherent to these claims. While we will continue to attempt to take appropriate precautions, we cannot assure that we will avoid significant product liability exposure.

On November 28, 2008, as we disclosed in an 8-K, we suspended product liability insurance for Alferon(R) N and Ampligen(R) until we receive regulatory clearance for Ampligen(R). We now require third parties to indemnify us in conjunction with all overseas emergency sales of Ampligen(R) and Alferon(R) LDO. We concluded that years of successfully addressing the limited number of product liability claims filed against Ampligen(R) and Alferon(R) LDO, combined with the mandatory patient waivers completed as an element of clinical trials and lack of any commercial sales since April 2008, that temporarily discontinuing the liability insurance was an acceptable risk given our financial condition and need to conserve cash.

Currently, without product liability coverage for Ampligen(R) and Alferon(R) LDO, a claim against the products could have a materially adverse effect on our business and financial condition.

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The loss of services of key personnel including Dr. William A. Carter could hurt our chances for success.

Our success is dependent on the continued efforts of our staff, especially certain doctors and researchers along with the continued efforts of Dr. William A. Carter because of his position as a pioneer in the field of nucleic acid drugs, his being the co-inventor of Ampligen(R), and his knowledge of our overall activities, including patents and clinical trials. As a result of our implementation of the Employee Wage Or Hours Reduction Program, our staff has agreed to take a portion of their compensation in shares of our Common Stock. While we believe that our employees are dedicated to us and while we have incentivised them to remain with us through the establishment of a Bonus Pool that would award them money in the event that the FDA approves our NDA for Ampligen(R), we cannot assure that they will remain with us. For information on the Employee Wage Or Hours Reduction Program and the Bonus Pool, please see "Item 11. Executive Compensation; Compensation Discussion and Analysis; Elements of Executive Compensation; Other Compensation." The loss of the services of personnel key to our operations or Dr. Carter could have a material adverse effect on our operations and chances for success. As a cash conservation measure, we have elected to discontinue the key man life insurance in the amount of $2,000,000 on the life of Dr. Carter until we receive regulatory clearance for Ampligen(R). An employment agreement continues to exist with Dr. Carter that, as amended, runs until December 31, 2010. However, Dr. Carter has the right to terminate his employment upon not less than 30 days prior written notice. The loss of Dr. Carter or other personnel or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

Uncertainty of health care reimbursement for our products.

Our ability to successfully commercialize our products will depend, in part, on the extent to which reimbursement for the cost of such products and related treatment will be available from government health administration authorities, private health coverage insurers and other organizations. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and from time to time legislation is proposed, which, if adopted, could further restrict the prices charged by and/or amounts reimbursable to manufacturers of pharmaceutical products. We cannot predict what, if any, legislation will ultimately be adopted or the impact of such legislation on us. There can be no assurance that third party insurance companies will allow us to charge and receive payments for products sufficient to realize an appropriate return on our investment in product development.

There are risks of liabilities associated with handling and disposing of hazardous materials.

Our business involves the controlled use of hazardous materials, carcinogenic chemicals, flammable solvents and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply in all material respects with the standards prescribed by applicable regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident or the failure to comply with applicable regulations, we could be held liable for any damages that result, and any such liability could be significant. We do not maintain insurance coverage against such liabilities.

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Risks Associated With an Investment in Our Common Stock

The market price of our stock may be adversely affected by market volatility.

The market price of our common stock has been and is likely to be volatile. This is especially true given the current significant instability in the financial markets. In addition to general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

- announcements of the results of clinical trials by us or our competitors;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- changes in U.S. or foreign regulatory policy during the period of product development;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries;
- new accounting standards;
- overall investment market fluctuation; and
- occurrence of any of the risks described in these "Risk Factors."

Our common stock is listed for quotation on the NYSE Alternext US (formerly, the American Stock Exchange). For the 12-month period ended December 31, 2008, the price of our common stock has ranged from $0.25 to $1.20 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. If we face securities litigation in the future, even if without merit or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

Our stock price may be adversely affected if a significant amount of shares are sold in the public market.

In connection with entering into the Purchase Agreement with Fusion

Capital Fund II, LLC ("Fusion")in August 2008, we registered 21,300,000 shares in the aggregate, consisting of 20,000,000 shares which we may sell to Fusion and 1,300,000 shares we have issued or may issue to Fusion as Commitment Shares. The number of shares ultimately offered for sale by Fusion is dependent upon the number of shares purchased by Fusion under the agreement. The purchase price for the common stock to be sold to Fusion pursuant to the Purchase Agreement will

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fluctuate based on the price of our common stock. Under the rules of the NYSE Alternext US, we may not issue more than 14,823,651 shares (19.99% of our outstanding shares as of July 2, 2008, the date of the purchase agreement) without first obtaining the approval of stockholders. In November 2008, we received stockholder approval to issue the additional 6,476,349 shares. It is anticipated that shares registered could be sold over a period of up to 25 months after the registration statement is declared effective. Depending upon market liquidity at the time, a sale of shares by Fusion at any given time could cause the trading price of our common stock to decline. Fusion may ultimately purchase all, some or none of the 20,000,000 shares of common stock to be registered but not yet issued. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to Fusion by us under the Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by Fusion, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares to Fusion and the agreement may be terminated by us at any time at our discretion without any cost to us.

In addition to the 21,300,000 shares registered for Fusion, we have previously registered 135% of 3,615,514 shares issuable upon exercise of Warrants related to our former convertible debentures and 14,442,294 shares issuable upon exercise of certain other warrants. To the extent the exercise price of the warrants is less than the market price of the common stock, the holders of the warrants are likely to exercise them and sell the underlying shares of common stock and to the extent that the conversion price and exercise price of these securities are adjusted pursuant to anti-dilution protection, the securities could be exercisable or convertible for even more shares of common stock. We also may issue shares to be used to meet our capital requirements or use shares to compensate employees, consultants and/or directors. In this regard we previously registered $50,000,000 worth of our securities in a universal shelf registration statement, none of which has been designated or issued. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock.

Sales of substantial amounts of our common stock in the public market could cause the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities.

Provisions of our Certificate of Incorporation and Delaware law could defer a change of our management which could discourage or delay offers to acquire us.

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of

Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the
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preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, in November 2002, we adopted a stockholder rights plan and, under the Plan, our Board of Directors declared a dividend distribution of one Right for each outstanding share of Common Stock to stockholders of record at the close of business on November 29, 2002. Each Right initially entitles holders to buy one unit of preferred stock for $30.00. The Rights generally are not transferable apart from the common stock and will not be exercisable unless and until a person or group acquires or commences a tender or exchange offer to acquire, beneficial ownership of 15% or more of our common stock. However, for Dr. Carter, our Chief Executive Officer, who already beneficially owns 7.7% of our common stock, the Plan's threshold will be 20%, instead of 15%. The Rights will expire on November 19, 2012, and may be redeemed prior thereto at $.01 per Right under certain circumstances.

Special Note Regarding Forward Looking Statements

Because the risk factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Our research in clinical efforts may continue for the next several years and we may continue to incur losses due to clinical costs incurred in the development of Ampligen(R) for commercial application. Possible losses may fluctuate from quarter to quarter as a result of differences in the timing of significant expenses incurred and receipt of licensing fees and/or cost recovery treatment revenues in Europe, Canada and the United States.

ITEM 1B. Unresolved Staff Comments.

None.

ITEM 2. Properties.

We currently lease our headquarters located in Philadelphia, Pennsylvania consisting of a suite of offices of approximately 9,000 square feet. We also currently own, occupy and use our New Brunswick, New Jersey laboratory and production facility that we acquired from ISI. These facilities consist of two buildings located on 2.8 acres. One building is a two story facility consisting of a total of 31,300 square feet. This facility contains offices, laboratories, production space and shipping and receiving areas. It is also contains space designated for research and development, our pharmacy, packaging, quality assurance and quality control laboratories. Building Two has 11,670 square feet consisting of offices, laboratories and warehouse space. The property has parking space for approximately 100 vehicles.

ITEM 3. Legal Proceedings.

Please see "Note 15 - Contingencies" under Notes to Consolidated

Financial Statements.

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ITEM 4. Submission of Matters to a Vote of Security Holders.

Our Annual Meeting of Stockholders initially held on September 17, 2008, was adjourned to October 17, 2008 and then November 11, 2008. The adjournments were due to an inability to obtain a quorum. Our Board of Directors amended our By-Laws to reduce the quorum solely for this meeting from a majority to 44% in voting power of the outstanding shares of stock entitled to vote at the meeting. At the meeting, stockholders approved the following:

Election of Directors:

Nominees	For	Withheld
William A. Carter	31,762,316	4,959,791
Richard C. Piani	31,912,275	4,809,832
William M. Mitchell	31,918,799	4,803,308
Iraj-Eqhbal Kiani, Ph.D.	31,730,192	4,991,915
Thomas K. Equels	32,524,699	4,197,408

Ratification of the appointment of McGladrey & Pullen, LLP as our independent accountants:

For: 35,911,303 Against: 845,300 Abstain: 117,733.

Approval of the issuance of our Common Stock to comply with AMEX Company Guide Section 713 (Shares voted for excluding 650,000 shares owned by Fusion Capital Fund II, LLC):

For: 12,089,859 Against: 1,355,887 Abstain: 103,215
Broker non-votes: 22,675,375.

Total shares voted: 36,874,336 out of 74,805,334 eligible to vote.

PART II

ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

In 2008, we issued shares of common stock consisting of 1) 2,677,640 shares in payment to vendors and consultants for services rendered; 2) 1,211,122 shares issued pursuant to the 2008 Purchase Agreement with Fusion; and 3) 339,636 shares to our Directors pursuant to our Directors' Compensation Program. In addition, in February 2009, we issued an aggregate of 982,392 warrants with an expiration period of ten years and exercise price of $0.51 per share to Dr. Carter and Mr. Equels, pursuant to the terms of the Standby Financing Agreement.

The foregoing issuances of securities were private transactions and exempt from registration under section 4(2) of the Securities Act and/or regulation D rule 506 promulgated under the Securities Act.

Since October 1997 our common stock has been listed and traded on the NYSE Alternext US (formerly, the American Stock Exchange) under the symbol HEB. The following table sets forth the high and low list prices for our Common Stock for the last two fiscal years as reported by the NYSE Alternext US. Such prices reflect inter-dealer prices, without retail markup, markdowns or commissions and may not necessarily represent actual transactions.

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COMMON STOCK	High	Low
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Time Period:		

January 1, 2008 through March 31, 2008	0.89	0.59
April 1, 2008 through June 30, 2008	1.00	0.62
July 1, 2008 through September 30, 2008	1.20	0.25
October 1, 2008 through December 31, 2008	0.70	0.25

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January 1, 2007 through March 31, 2007	2.49	1.60
April 1, 2007 through June 30, 2007	1.82	1.24
July 1, 2007 through September 30, 2007	1.79	1.06
October 1, 2007 through December 31, 2007	2.08	0.53

As of March 3, 2009, there were approximately 233 holders of record of our Common Stock. This number was determined from records maintained by our transfer agent and does not include beneficial owners of our securities whose securities are held in the names of various dealers and/or clearing agencies.

On March 3, 2009, the last sale price for our common stock on the NYSE Alternext US (formerly, the American Stock Exchange) was $0.41 per share.

We have not paid any cash dividends on our Common Stock in recent years. It is management's intention not to declare or pay dividends on our Common Stock, but to retain earnings, if any, for the operation and expansion of our business.

The following table gives information about our Common Stock that may be issued upon the exercise of options, warrants and rights under all of our equity compensation plans as of December 31, 2008.

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average Exercise price of Outstanding options, warrants and rights	Number of sec Remaining ava future issuan equity compen plans(excludi securities re column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders:	9,021,818	$2.54	3,932,894
Equity compensation plans not approved by security holders:	5,266,187	$3.12	
Total	14,288,005	$2.75	3,932,894

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Performance Graph

Total Return To Shareholders
(Includes reinvestment of dividends)

ANNUAL RETURN PERCENTAGE
Years Ending

Company Name / Index	Dec 04	Dec 05	Dec 06
Hemispherx Biopharma, Inc.	-15.93	14.21	1.38
S&P SmallCap 600 Index	22.65	7.68	15.12
Peer Group	-40.46	0.20	24.05

INDEXED RETURNS
Years Ending

Company Name / Index	Base Period Dec 03	Dec 04	Dec 05	Dec 06
Hemispherx Biopharma, Inc.	100	84.07	96.02	97.35
S&P SmallCap 600 Index	100	122.65	132.07	152.04
Peer Group	100	59.54	59.66	74.00

Peer Group Companies

AVI BIOPHARMA INC
CYTRX CORP.
GENVEC INC.
OXIGENE INC.

[GRAPHIC OMITTED][GRAPHIC OMITTED]

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ITEM 6. Selected Financial Data (in thousands except for share and per share data).

The selected consolidated financial data set forth below should be read in conjunction with our consolidated financial statements, and the related notes thereto, and "Management's Discussion and Analysis of Financial Condition and Results of Operations", included in this Annual Report. The statement of operations and balance sheet data presented below for, and as of the end of, each of the years in the five year period ended December 31, 2008 are derived from our audited consolidated financial statements. Historical results are not necessarily indicative of the results to be expected in the future.

Year Ended December 31	2004	2005	2006	2007
Statement of Operations Data:				
Revenues and License fee Income	$1,229	$1,083	$933	$1,059

Total Costs and Expenses(1)	12,118	10,998	19,627	20,348
Interest Expense and Financing Costs(2)	5,674	3,121	1,259	396
Net loss	(16,887)	(12,446)	(19,399)	(18,139)
Deemed Dividend	(4,031)	-	-	-
Net loss applicable to common stockholders	(20,918)	(12,446)	(19,399)	(18,139)
Basic and diluted net loss per share	(0.46)	(0.24)	(0.31)	(0.25)
Shares used in computing basic and diluted net loss per share	45,177,862	51,475,192	61,815,358	71,839,782
Balance Sheet Data:				
Working Capital	$ 13,934	$ 16,353	$16,559	$14,412
Total Assets	25,293	24,654	31,431	23,142
Debt, net of discount(3)	4,312	4,171	3,871	-
Stockholders' Equity	19,443	18,627	24,751	20,955
Cash Flow Data:				
Cash used in operatin activities	$ (7,240)	$ (7,231)	$(13,747)	$(15,112
Capital expenditures	(150)	(1,002)	(1,351)	(212

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(1) General and Administrative expenses include stock compensation expense of $2,000, $391, $2,483, $2,291 and $573 for the years ended December 31, 2004, 2005, 2006, 2007 and 2008, respectively.

(2) For information concerning our financing see Note 7 to our consolidated financial statements for the year ended December 31, 2008 contained herein.

(3) In accounting for the January 26, 2004 and July 13, 2004 issuances of 6% Senior Convertible Debentures in the principal amounts of $4,000, and $2,000, respectively, and related embedded conversion features and warrant issuances, we recorded debt discounts which, in effect, reduced the carrying value of the debt.

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis is related to our financial condition and results of operations for the three years ended December 31, 2008. This information should be read in conjunction with Item 6 - "Selected Financial Data" and our consolidated financial statements and related notes thereto beginning on F-1 of this Form 10-K.

Statement of Forward-Looking Information

Certain statements in the section are "forward-looking statements." You should read the information before Item 1B above, "Special Note" Regarding Forward-Looking Statements" for more information about our presentation of information.

Background

We are a biopharmaceutical company engaged in the manufacture and clinical development of new drug entities for treatment of seriously debilitating disorders. Our flagship products include Alferon N Injection(R) and the experimental therapeutics Ampligen(R) and Oragens. Alferon N Injection(R) is approved for a category of STD infection, and Ampligen(R) and Oragens represent experimental RNA nucleic acids being developed for globally important viral diseases and disorders of the immune system. Hemispherx's platform technology includes large and small agent components for potential treatment of various severely debilitating and life threatening diseases. We have in excess of 50 patents comprising our core intellectual property estate, a product (Alferon N Injection(R)) and GMP certified manufacturing facilities for our novel pharmaceutical products.

We have reported net income only from 1985 through 1987. Since 1987, we have incurred, as expected, substantial operating losses due to our conducting research and development programs.

RESULTS OF OPERATIONS

Year ended December 31, 2007 versus December 31, 2008

Net loss

Our net loss of approximately $12,219,000 for the year ended December 31, 2008 was 33% lower when compared to the same period in 2007. This $5,920,000 reduction in loss was primarily due to:

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1) Research and Development costs in 2007 included significant expenses related to the preparation of the Ampligen(R) NDA as well as expenses related to the production of Ampligen(R) for use in stability studies and preparation of pre commercial lots for regulatory review purposes. Research and development expenses in 2008 were down approximately $4,644,000 as compared to the same period in 2007.

2) Alferon N Injection(R) had seen increased competition from the use of topical solutions for genital warts. Additionally, there were no sales of Alferon N Injection(R) for the last nine months of 2008 as finished goods inventory has reached its current product expiration date of March 31, 2008. Sales of Alferon N Injection(R) for the twelve months ended December 31, 2008 and 2007 amounted to approximately $173,000 and $925,000, respectively for a reduction of $752,000 or 81%.

3) General and administrative expenses decreased approximately $2,496,000 during the twelve months ended December 31, 2008 versus the same period a year ago primarily due to reductions in the cost of non-cash Stock Compensation of $1,718,000, Director Fees for $137,000, Impairment Charges for $562,000 and Accounting Fees of $34,000 that were offset with an increase of Legal Fees for $635,000 resulting from litigation expenses.

Impairment charges of $526,000 incurred during the year ended December 31, 2007 primarily due to the write-down of Royalty Interest of patents acquired from ISI on Alferon N Infection(R)

and charges taken against a water purification system that was determined not needed for use at the New Brunswick, NJ facility due to a change in manufacturing plans.

4) Interest and other income decreased $608,000 or 51% for the twelve months ended December 31, 2008 as compared to the same period in 2007 due to a reduction of funds available to invest as compared to the prior period and compounded by lower the interest rates.

5) Production/Cost of Goods Sold were lower in 2008 by $132,000. This decrease reflects a lower cost of sales in 2008 offset by fixed costs in manufacturing which could not be applied Inventory due to the halting of Alferon(R) N production.

6) In September 2007, an increase of $346,000 in other income occurred due to the reversal of accrued liquidated damages in 2006 with respect to our debentures. These damages related to certain debenture covenants were settled without charge in the maturation and pay down of the debenture holder's outstanding loan balances in 2007.

Net loss per share was $(0.16) for the current period versus $(0.25) for the same period in 2008.

Revenues

Revenues for the year ended December 31, 2008 were $265,000 as compared to revenues of $1,059,000 for the same period in 2007. Ampligen(R) sold under the cost recovery clinical program was down $42,000 and Alferon N Injection(R) sales were down $752,000 or 81% as compared to the prior period.

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Ampligen(R) sold under the cost recovery clinical program is a product of physicians and ME/CFS patients applying to us to enroll in the program. This program has been in effect for several years and is offered as a treatment option to patients severely affected by CFS. As the name "cost recovery" implies, we have no gain or profit on these sales. The benefits to us include 1) physicians and patients becoming familiar with Ampligen(R); and 2) collection of clinical data relating to the patients' treatment and results. Revenues from our Ampligen(R) cost recovery program were down 32% as fewer patients are participating in the program. Our clinical staff has not encouraged cost recovery clinical enrollments in order that our internal resources could address the Ampligen(R) New Drug Application ("NDA") and related documents preparatory to filing for a full commercial license.

The primary reason for the 81% drop in the sales Alferon(R) for the twelve months ended December 31, 2008 is that commercial sales of Alferon N Injection(R) were halted in April 2008 as the expiration date of our finished good inventory expired in March 2008. As a result, we had no product to sell for the last nine months of 2008.

Production costs/cost of goods sold

Production/cost of goods sold was approximately $930,000 and $798,000, respectively, for the twelve months ended December 31, 2007 and 2008. This represented a decrease of approximately $132,000 or 14% as compared to the same period in 2007. These costs primarily represent: 1) costs of goods sold of approximately $381,000 and $-0-, respectively, for the twelve months ended December 31, 2007 and 2008; and 2) Costs to maintain Alferon N Injection(R) Inventory including storage, stability testing and reporting costs incurred in our attempt to have the FDA extend the commercial sales life of our Alferon N Injection(R) Finished Goods. The primary reason for the decrease in cost of

goods sold can be attributed to the lack of Alferon N Injection(R) sales since April 1, 2008 and its impact on costs of goods sold.

Research and Development Costs

Overall research and development costs for the twelve months ended December 31, 2008 were $5,800,000 as compared to $10,444,000 for the same period a year ago reflecting a decrease of $4,644,000 or 44%. This decrease was primarily due to reduced outside consulting fees and other costs related to the preparation and filing of our NDA for Ampligen(R).

On July 7, 2008 we were notified that the FDA had accepted for review our amended NDA filing for using Ampligen(R) to treat CFS. FDA approval of this application would provide the first-ever treatment for CFS. At present, only supportive symptom-based care is available for CFS patients. While we are optimistic, there are no assurances that the NDA will be approved. Over the summer of 2008, our clinical monitors visited our sites associated with our AMP-511 cost recovery treatment program for the collection and audit of additional data to be submitted to the FDA in support of our NDA for CFS currently under review. FDA inspections of several clinical sites did not result in the issuance of any "483" reports indicating lack of compliance with various regulations governing clinical trials. On February 18, 2009, we were notified by the FDA that the originally scheduled Prescription Drug User Fee Act ("PDUFA") date of February 25, 2009 has been extended to May 25, 2009. For more information on our NDA, please see "Note 19:
Subsequent Events" under Notes to Consolidated Financial Statements.
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In 2008, we spent considerable time and effort preparing for the preapproval inspection by the U.S. FDA for manufacturing of Ampligen(R) product and its raw materials, polynucleotides Poly I and Poly C12U. A satisfactory recommendation from the FDA Office of Compliance based upon an acceptable preapproval inspection is required prior to approval of the product. The preapproval inspection determines compliance with current Good Manufacturing Practices (cGMPs) as well as a product specific evaluation concerning the manufacturing process of product. The inspection includes many aspects of the cGMP requirements, such as manufacturing process validation, equipment qualification, analytical method validation, facility cleaning, quality systems, documentation system and part 11 compliance.

The New Jersey District Office of the FDA conducted an inspection of the New Brunswick, New Jersey facility in late January and early February 2009 (nine days total). A one-page Form FDA 483 was issued citing a need to re-perform four method validations to generate data in the New Brunswick Laboratories. These validations had been performed at another site also owned and operated by us prior to transferring the equipment to New Brunswick. We anticipate that the validations will be re-performed and completed at the New Brunswick site within three months.

The FDA conducted a field inspection at Hollister-Stier Laboratories in Spokane, Washington in mid-2008 (June 19 to July 2, 2008). The Ampligen(R) final fill operations are performed under contract with Hollister-Stier. The inspection resulted in a Form FDA 483 with two observations dealing with reviews and validations of process variability. We are working with Hollister-Stier to finalize specific actions.

On September 19, 2008, we executed an agreement with Lovelace Respiratory Research Institute in Albuquerque, New Mexico to perform certain animal toxic studies in support of our Ampligen(R) NDA. These studies were requested by the FDA and will be done in collaboration with the resources of the New Brunswick facility. We expect these studies to be complete in April 2009.

We are also engaged in ongoing, experimental studies assessing the efficacy of Ampligen(R), Alferon N Injection(R), and Alferon(R) LDO against influenza viruses as a single adjuvant agent antiviral with Japan's National Institute of Infectious disease, Biken (the non-profit operational arm of the Foundation for Microbial Diseases of Osaka University) and St. Vincent's Hospital in Darlinghurst, Australia. As a result of focusing our limited resources on the Australian and Japanese studies, no further experiments have been undertaken by the Defence R&D Canada with respect to their independent study assessing the efficacy of Ampligen(R) against Influenza viruses as a single agent antiviral.

The Biken arrangement was concluded in December 2007 and basically consists of Biken purchasing Ampligen(R) for use in conducting further animal studies of intranasal prototype vaccines containing antigens from influenza sub-types H1N1, H3N2 and B progressing to human studies with all programs supported by the Japanese Health Ministry. Under the terms of the non--exclusive licensing arrangement, we will receive royalties as well as income for all Ampligen(R) used in the ongoing experimental work and any subsequent marketing of Ampligen(R) as an immuno-enhancer for flu vaccines delivered intranasally in Japan. To date, only two or three pharma companies worldwide have achieved regulatory authorizations to sell intranasally (IN) administered influenza vaccines versus many companies receiving approval for intramuscular vaccine delivery routes. Safety has been paramount in developing effective treatments. However, animal studies to date indicate Ampligen(R), an experimental drug, may be safely administered intranasally. Clinical studies (in other disorders) have
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built a database of more than 90,000 injections of Ampligen(R) when given parenterally (intravenous, or "IV"). In June 2008, Biken notified us they were accelerating their program and were shipped additional Ampligen(R) supplies for various preclinical vaccine studies and research projects that remain in progress. A secondary goal of the trial is to evaluate whether antibodies stimulated by the vaccine/Ampligen(R) combination also provide protection against H5N1, the avian influenza virus. Since 2003, the World Health Organization has confirmed 407 cases and attributed 254 human deaths worldwide to H5N1. Investigators from Japan's Institute of Infectious Disease have conducted studies in animals that suggest that Ampligen(R) can stimulate a sufficiently broad immune response to provide cross-protection against a range of virus strains, including H5N1.

The clinical trial in Australia is using Ampligen(R) in combination with seasonal flu vaccine. This open-label study (Phase IIa) utilizing Ampligen(R) (Poly I: Poly C12U) as a potential immune-enhancer was conducted in Australia with thirty-eight subjects age 60 or greater with the standard trivalent seasonal influenza vaccines. Ampligen(R) was administered subcutaneously. Elderly subjects typically have reduced immune responses relative to younger populations. The combinational treatment was generally well-tolerated. Serologic studies to evaluate the magnitude and spectrum of immune response are pending and are expected by mid-2009; however, only certain labs are qualified to conduct these tests and during the course of the clinical testing, one of these testing labs changed ownership. We are in the process of determining that the methodology remained validated and consistent with the pilot results obtained about a year earlier with a smaller group consisting of the first 8 enrolled subjects.

As reported in the Journal of American Medical Association in 2003 by Thompson, Shay, Weintraub, Brammer, Cox, Anderson, et al. seasonal influenza kills approximately 36,000 Americans annually, most over the age of 70. In 2004 in JAMA, the same authors attributed 200,000 U.S. hospital admissions annually to seasonal flu.

Collaboration studies in non-human primates conducted by ViroClinics in the Netherlands suggest a potential role for Alferon(R) LDO as another novel

therapeutic approach to viral pandemics. Meetings with prospective partners are underway with respect to conducting clinical trials using Alferon LDO to treat and/or prevent seasonal influenza in the Pacific Rim countries. Alferon LDO is now poised for clinical trials against seasonal influenza epidemics; meetings with prospective partners are ongoing to conduct clinical trials in the Pacific Rim countries and elsewhere. The opportunity for Alferon(R) LDO is reinforced by new reports of severe side effects secondary to Tamiflu, the present standard of care, by both the FDA and Japanese health authorities. Also, Tamiflu resistant strains of flu virus are now raising serious concerns on a world-wide basis.

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General and Administrative Expenses

General and Administrative ("G&A") expenses for the twelve months ended December 31, 2007 and 2008 were approximately $8,974,000 and $6,478,000, respectively, reflecting a decrease of $2,496,000 or 28% primarily due to reductions in the cost of non-cash Stock Compensation of $1,718,000, Director Fees for $137,000, Impairment Charges of $526,000, Accounting Fees of $34,000 and various other general administrative expenses that were partially offset by an increase of Legal Fees for $635,000 resulting from litigation to settle existing suits.

In 2007, we incurred impairment charges amounting to $526,000 as compared to no such charges in the current year. The primary reason for these charges stemmed from the $228,000 write-down of a water purification system that was determined to be unnecessary at our New Jersey facility due to a change in manufacturing plans. Additionally in 2007, we wrote down the value of our intangible asset associated with the repurchase of a 6% Royalty on Alferon N Injection(R) sales by $298,000. We determined in 2007 that we did not have sufficient inventory on hand to realize the full economic benefit of this asset; therefore, it was written down to its net realizable value.

Reversal of Previously Accrued Interest Expense

In September 2007, and increase of $346,00 in other income occurred due to the reversal of accrued liquidated damages in 2006 with respect to our debentures holders. These damages related to certain debenture covenants were settled without charge in the maturation and pay down of the debenture holder's outstanding loan balance in 2007.

Interest and Other Income

Interest and other income for the year ended December 31, 2007 and 2008 was $1,200,000 and $592,000, respectively, representing a decrease of $608,000 or 51%. The decrease in interest and other income during the current period was mainly due to a reduction in funds available for Short Term Investments compounded by the lower interest rates.

Interest Expense and Financing Costs

We had no interest expense or non-cash financing costs for the twelve months ended December 31, 2008 as compared to $396,000 for the same period a year ago. The expenses reflected for the year ended 2007 reflect financing costs and interest charges related to our convertible debentures which matured in June 2007 when all outstanding loan balances were paid.

Year ended December 31, 2006 versus December 31, 2007

Net loss

Our net loss of approximately $18,139,000 for the year ended December 31, 2007 was 6.5% lower when compared to the same period in 2006. This

$1,260,000 reduction in loss was primarily due to:

1) Higher Interest and Other Income of approximately $646,000 mainly due to higher interest earned upon the maturity of our marketable securities as compared to the same period a year ago;

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2) Lower interest expense and financing costs of $863,000 in 2007 relating to the amortization of debt discounts on our convertible debentures and the incurring of liquidated damages in 2006 payable to our debenture holders resulting from us failing to timely file our 2005 Annual Report on Form 10-K; and

3) An increase of $346,000 in other income due to a reversal of accrued liquidated damages in 2006 with respect to our debentures holders as a result of our failure to timely file our 2005 Annual Report on Form 10-K. These damages related to certain debenture covenants settled without charge in the maturation and pay down of the debenture holder's outstanding loan balances in 2007.

Net loss per share was $(0.25) for the current period versus $(0.31) for the same period in 2006.

Revenues

Revenues for the year ended December 31, 2007 were $1,059,000 as compared to revenues of $933,000 for the same period in 2006. Ampligen(R) sold under the cost recovery clinical program was down $49,000 or 27% and Alferon N Injection(R) sales were up $175,000 or 23% as compared to the prior period. Ampligen(R) sold under the cost recovery clinical program is a product of physicians and ME/CFS patients applying to us to enroll in the program. This program has been in effect for several years and is offered as a treatment option to patients severely affected by CFS. As the name "cost recovery" implies, we have no gain or profit on these sales. The benefits to us include 1) physicians and patients becoming familiar with Ampligen(R) and 2) collection of clinical data relating to the patients' treatment and results.

We altered our marketing strategy for Alferon N Injection(R) by relaunching the product via a collaborative marketing initiative between Hemispherx and a national Specialty Pharmacy network encompassing specialty pharmacists, pharmacies and targeted physician specialists. This effort was intended to focus our efforts in the most appropriate and productive market segment for the product. While Alferon N dollar sales are up from 2006, unit sales are down which reflects the effect of the price increase put into place in February 2007.

Production costs/cost of goods sold

Production/cost of goods sold was approximately $930,000 during the current period representing a decrease of approximately $345,000 or 27% as compared to the same period in 2006. This decrease was primarily due to lower production costs of $199,000 relating to excess production capacity during the prior period as more effort was directed toward Ampligen(R) research and development and the NDA; and a decrease in costs of goods sold of $146,000. Costs of goods sold for the year ended December 31, 2006 and 2007 was $527,000 and $381,000, respectively.

The primary reason for the decrease can be attributed to a decrease in unit sales in the current year versus the prior year. We outsourced certain components of our overall research and development, manufacturing, marketing and distribution while maintaining control over the entire process through our quality assurance group and our clinical monitoring group.

Research and Development costs

Overall research and development costs for the year ended December 31, 2007 were $10,444,000 as compared to $10,127,000 for the same period a year ago 39
representing an increase of $317,000 or 3%. These costs are primarily related to the collection and processing of clinical data, including the costs of establishing our in-house polymer production facility and the costs of preparing and completing our NDA for the use of Ampligen(R) in treating CFS. The year to year increase can be basically attributed to an increase in the use of consultants related to the preparation of our Ampligen(R) NDA.

Our primary focus in 2007 was on the preparation of the NDA for using Ampligen(R) to treat patients affected with CFS. In addition, we documented our polymer production process in anticipation of an FDA inspection. Three lots of liquid Ampligen(R) were produced for use in testing and stability studies. We finalized the filing of our Ampligen(R) NDA on October 7, 2007.

Much of our R&D cost is related to production of raw materials at our new production line installed at our New Brunswick facility. This facility produces Poly I and Poly C12U for use by Hollister-Stier (our contract manufacturer) in the manufacture of Ampligen(R). The first pilot production runs are being used for stability testing. Later commercial sized runs are being used for process validation and clinical use.

In addition, we are engaged in broad based, ongoing, experimental studies assessing the efficacy of Ampligen(R), Alferon N Injection(R), and Alferon LDO against influenza viruses as an adjuvant single agent antiviral with Defence R&D Canada, Japan's National Institute of Infectious disease, Biken (the non-profit operational arm of the Foundation for Microbial Diseases of Osaka University) and St. Vincent's Hospital in Darlinghurst, Australia.

The Biken arrangement was concluded in December 2007 and basically consists of Biken purchasing Ampligen(R) from us for use in conducting further animal studies of intranasal prototype vaccines containing antigens from influenza sub-types H1N1, H3N2 and B progressing to human studies with all programs supported by the Japanese Health Ministry. Under the terms of the non--exclusive licensing arrangement, we will receive royalties as well as income for all Ampligen(R) used in the ongoing experimental work and any subsequent marketing of Ampligen(R) as an immuno-enhancer for flu vaccines delivered intranasally in Japan. To date, only 2 or 3 pharma companies worldwide have achieved regulatory authorizations to sell intranasally (IN) administered influenza vaccines versus many companies receiving approval for intramuscular vaccine delivery routes. Safety has been paramount in developing effective treatments. However, animal studies to date indicate Ampligen(R), an experimental drug, may be safely administered intranasally. Clinical studies (in other disorders) have built a database of more than 90,000 injections of Ampligen(R) when given parenterally (intravenous, or "IV").

In September 2007, Japan's National Institute of Infectious Disease ("JNIID") initiated research on the co-administration of JNIID's HIV-1 vaccine with our experimental TLR3 agonist a substance that binds to a specific receptor and triggers a host defense response in the cell) and immune enhancer, Ampligen(R). This research is the result of earlier research suggesting a potential role for Ampligen(R) in boosting responses to certain vaccines designed to combat avian influenza (Bird Flu) as well as seasonal influenza viruses. The objective of this research is to determine if Ampligen(R) can overcome the historical problem which has handicapped AIDS vaccine development, namely marginal immune response which undermines the potential of long-lasting protection. Ampligen(R) will be combined with HIV recombinant protein and administered via an intranasal route.

In June 2007, we initiated a clinical trial in Australia using Ampligen(R) in combination with seasonal flu vaccine. This trial, expected to 40
continue for several months, is being conducted in Australia's winter season and focuses on populations at risk for virulent cases of influenza, especially those over the age of 60 years who historically may have weakened immune systems. The Australian clinical trial was prompted by the results from the pre-clinical work conducted by the JNIID (see above). Thirty patients were enrolled in this study, which utilized a two dose Ampligen(R) regimen of 2 mg per dose. This study was monitored by Clinical Network Services Pty. Ltd. located in Brisbane, Australia. The clinical trials center of St. Vincent's Hospital based in Darlinghurst, Australia conducted the trial. The clinical data from this trial is currently being analyzed with the results expected by mid-2009.

The CDC reports that the number of mosquito-borne West Nile Virus ("WNV") infections in the United States is "up sharply" over the same period in 2006. This increased infection rate has accelerated the enrollment of patients in our Phase IIb clinical trial using Alferon N(TM) to treat WNV patients. In lab studies, Alferon(R) N, a natural cocktail of eight alpha-interferons, shows synergistic effects (up to 100 fold over recombinant interferons) against pathogens such as WNV. The Phase IIb clinical trial is a double-blinded, randomized, multi-center program under the direction of Cornell University and Weill Cornell Medical College/New York Hospital.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the year ended December 31, 2006 and 2007 were approximately $8,225,000 and $8,974,000, respectively, reflecting an increase of $749,000 or 9%. This increase related primarily to an increase in legal and professional fees of $325,000 primarily due to on-going litigation involving Bioclones, increase in travel related expenses of $87,000 and increases in salaries and wages of $398,000 mainly resulting from the hire of our chief operating officer during the 4th quarter 2006. These increases in general and administrative costs were offset by lower accounting fees of $545,000 in 2007. The decrease in accounting fees was primarily due to charges incurred by us in 2006 related to the restatements to our financial statements in 2005. Lastly, we incurred impairment losses in 2007 amounting to $526,000 as compared to no such charges in the prior year. The primary reason for these charges stemmed from the $228,000 write-down of a water purification system that was determined to be unnecessary at our New Jersey facility due to a change in manufacturing plans. In addition, we wrote down the value of our intangible asset associated with the repurchase of a 6% Royalty on Alferon N Injection sales by $298,000. We determined that we did not have sufficient inventory on hand to realize the full economic benefit of this asset; therefore, it was written down to its net realizable value.

Reversal of Previously Accrued Interest Expense

Reversal of previously accrued interest expense was $346,000 for the year ended December 31, 2007. This item, classified as other income, resulted from the reversal of accrued liquidated damages in 2006 related to a certain covenant in our debenture agreements. These charges were incurred as a result of our failure to timely file our 2005 Annual Report on Form 10-K and our report on Form 10-Q for the quarterly period ended March 31, 2006 with the SEC pursuant to the 1934 Act. These liquidated damages were not included as part of the maturation and pay down of the debenture holder's outstanding loan balances.

Interest and Other Income

Interest and other income for the year ended December 31, 2006 and 2007 increased approximately $646,000 as compared to the same period a year earlier. The increase in interest and other income during the current period was mainly

due to higher interest earned upon the maturity of our marketable securities as compared to the same period a year ago.

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Interest Expense and Financing Costs

Interest expense and non-cash financing costs were approximately $396,000 for the year ended December 31, 2007 versus $1,259,000 for the same period a year ago. The main reason for the decrease in interest expense and financing costs of $863,000 or 69% can be attributed to decreased amortization charges on debt discounts and the incurring of liquidated damages in 2006 payable to our debenture holders resulting from our failure to timely file our 2005 Annual Report on Form 10-K as we were in violation of provisions within our debenture agreements. These debentures matured in June 2007 and all outstanding loan balances were paid off.

Liquidity and Capital Resources

Cash used in operating activities for the year ended December 31, 2008 was $9,358,000 reflecting mainly expenditures for the preparation and filing of the Ampligen(R) NDA. Cash provided by investing activities for the year ending December 31, 2008, amounted to $3,736,000, primarily from the maturity of short-term investments. Cash provided by financing activities for the year ended December 31, 2008 amounted to $270,000, basically from the sale of common stock. As of February 28, 2009 we had approximately $5,734,000 in cash and cash equivalents and short-term investments, or a decrease of approximately 6.3% from December 31, 2008.

Given the harsh economic conditions, we have reviewed every aspect of our operations for cost and spending reductions to assure the long-term survival of our Company while maintaining the resources necessary to achieve our primary objectives of obtaining NDA approval of Ampligen(R) and securing a strategic partner. We believe, but cannot assure, that our current funds should be sufficient to meet our operating cash requirements for the next 16 months as we have taken the steps discussed below to curtail discretionary spending to conserve cash and reduce our monthly burn rate. Please see Item 1A. Risk Factors, "We may require additional financing which may not be available."

In an effort to conserve Company cash, the Employee Wage Or Hours Reduction Program (the "Program") was ratified by the Board effective January 1, 2009. In a mandatory program that is estimated to be in effect for up to six months, compensation of all active full-time employees as of January 1, 2009 ("Participants") were reduced through a reduction in their wages for which they would be eligible to receive shares of our common stock ("Stock") six months after the shares were earned. While all employees were also offered the option to reduce their work hours with a proportional decease in wages, none elected this alternative. For more information, please see "Item 11. Executive Compensation; Compensation Discussion and Analysis; Elements of Executive Compensation; Other Compensation."

In addition, certain vendors and service providers have agreed to accept shares of our Common Stock as partial payment of their bills. In 2008, we issued 3,017,276 shares of common stock for services rendered.

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Notwithstanding our cost and spending reduction activities, we may need to raise additional funds through additional equity or debt financing or from other sources in order to complete the necessary clinical trials and the regulatory approval processes including the commercializing of Ampligen(R) products. There can be no assurances that we will raise adequate funds from these or other sources, especially considering current adverse market conditions, which may have a material adverse effect on our ability to develop our products. Any additional funding may result in significant dilution and

could involve the issuance of securities with rights, which are senior to those of existing stockholders. We may also need additional funding earlier than anticipated, and our cash requirements, in general, may vary materially from those now planned, for reasons including, but not limited to, changes in our research and development programs, clinical trials, competitive and technological advances, the regulatory process, and higher than anticipated expenses and lower than anticipated revenues from certain of our clinical trials for which cost recovery from participants has been approved.

We have been using the proceeds from financing to fund infrastructure growth including manufacturing, regulatory compliance and market development. Due to current market conditions, we have been unable to consistently raise funds pursuant to the terms of the Fusion Purchase Agreement (see "Equity Financing" below).

Standby Financing Agreement

In February 2009, we entered into a Standby Financing Agreement pursuant to which certain individuals ("Individuals"), consisting of Dr. Carter and Thomas Equels, agreed to loan us up to an aggregate of $1,000,000 in funds should we be unable to obtain additional financing, if needed. Under the Standby Financing Agreement, we will use our best efforts in 2009 to obtain one or more additional financing agreements on such terms as our Board deems to be reasonable and appropriate in order to maintain our operations. If at any time after December 1, 2009 and prior to June 30, 2010 a majority of our independent Directors deems that in the event a financing of at least $2.5 Million has not been obtained and additional funds are needed to maintain our operations, we will send a written notice to each of the Individuals informing them of the total amount of additional funds required and the specific amount that will be required from each Individual. Within fifteen calendar days after receipt of the notice, the Individuals will be required to pay us their respective amount. We will then issue to them one year 15% senior secured notes for their respective amounts (the "Notes"). Interest will be paid monthly in our Common Stock. Repayment of the principal and interest under the Notes will be secured by all of our assets. We will not, without the consent of the Individuals, (i) incur any new debt senior or pari passu to the Notes or (ii) encumber or grant a security interest in any assets. Upon 20 business days written notice, we may prepay the Notes in cash at any time at 105% of the then outstanding principal amount of the Notes, plus any accrued but unpaid interest.

For agreeing to be obligated to loan us money, each Individual received 10 year warrants (the "Commitment Warrants") to purchase our common stock at the rate of $50,000 worth in warrants per $100,000 committed. The exercise price of these warrants is $0.51 (125% of the market closing price of our Common Stock on the date that Agreement was executed. These warrants vested immediately. If and when we notify the Individuals that we are consummating the Standby Financing, upon each Individual's payment of his committed amount, he will receive additional 10 year warrants to purchase our Common Stock at the rate of $50,000 worth in warrants per $100,000 paid. The exercise price of the warrants will be

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the closing market price of our Common Stock on the day we receive the funds from the Individuals. These warrants will vest immediately. While any portion of the Notes are outstanding, Individuals will have weighted average anti-dilution rights with regard to the exercise price of all warrants issued pursuant hereto except that these rights will not apply if the securities are issued to employees, Board members, corporate and scientific advisors, select vendors, pursuant to our current agreement with Fusion Capital Fund II, LLC or part of a corporate or strategic alliance.

Equity Financing

In July 2008, we entered into a $30 million Common Stock Purchase

Agreement (the "Purchase Agreement") with Fusion Capital Fund II, LLC ("Fusion"), an Illinois limited liability company. Concurrently with entering into the Purchase Agreement, we entered into a registration rights agreement with Fusion. Pursuant to the registration rights agreement, we filed a registration statement related to the transaction with the U.S. Securities and Exchange Commission ("SEC") covering 21,300,000 shares that have been issued or may be issued to Fusion under the Purchase Agreement. The SEC declared effective the registration statement on August 12, 2008. We have the right over a 25 month period to sell our shares of common stock to Fusion from time to time in amounts between $120,000 and $1 million depending on certain conditions as set forth in the agreement, up to a maximum of $30 million. The purchase price of the shares related to the $30.0 million of future funding will be based on the prevailing market prices of our shares at the time of sales as computed under the Purchase Agreement without any fixed discount, and we will control the timing and amount of any sales of shares to Fusion. Fusion shall not have the right or the obligation to purchase any shares of our common stock on any business day that the price of our common stock is below $0.40. Recently, the price of our common stock has consistently fallen been below $0.40 and, accordingly, no additional sales can be made to Fusion unless and until the price rises to $0.40 per share or better for 12 consecutive business days. The Purchase Agreement may be terminated by us at any time at our discretion without any cost to us. There are no negative covenants, restrictions on future funding, penalties or liquidated damages in the agreement. In consideration for entering into the Purchase Agreement, upon execution of the Purchase Agreement we issued to Fusion 650,000 shares as a commitment fee. Also, we will issue to Fusion up to an additional 650,000 shares as a commitment fee pro rata as we receive up to the $30.0 million of future funding.

Under the rules of the NYSE Alternext US, we may issue no more than 14,823,651 shares (19.99% of our outstanding shares as of July 2, 2008, the date of the purchase agreement) without first obtaining the approval of stockholders. That approval was obtained on November 11, 2008. As of December 31, 2008, we have executed transactions pursuant the Fusion Stock Purchase Agreement valued at $270,000 and 1,211,122 shares, which includes 650,000 shares as the initial fee for the financing.

The proceeds from this financing have been used to fund infrastructure growth including manufacturing, regulatory compliance and market development.

In April 2006 we entered into a prior common stock purchase agreement with Fusion, pursuant to which we sold an aggregate of 10,682,032 shares for total gross proceeds of approximately $19,739,000 through November, 2007. This agreement expired on July 31, 2008.

Because of our long-term capital requirements, we may seek to access the public equity market whenever conditions are favorable, even if we do not

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have an immediate need for additional capital at that time. In this regard we also have previously registered $50,000,000 worth of our securities in a universal shelf registration statement, none of which has been designated or issued. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock. Any additional funding may result in significant dilution and could involve the issuance of securities with rights, which are senior to those of existing stockholders. We may also need additional funding earlier than anticipated, and our cash requirements, in general, may vary materially from those now planned, for reasons including, but not limited to, changes in our research and development programs, clinical trials, competitive and technological advances, the regulatory processes, including the commercializing of Ampligen(R) products.

There can be no assurances that we will raise adequate funds from these

or other sources, which may have a material adverse effect on our ability to develop our products. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash.

	(dollars in thousands) Obligations Expiring by Period			
Contractual Cash Obligations	Total	2009	2010	2011
Operating Leases	$229	$171	$58	$-0-
Total	$229	$171	$58	$-0-

New Accounting Pronouncements

Refer to "Note 2(l) - Recent Accounting Standards and Pronouncements" under Notes to Consolidated Financial Statements.

Disclosure About Off-Balance Sheet Arrangements

None.

Critical Accounting Policies

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our significant accounting policies are described in the Notes to Consolidated Financial Statements. The significant accounting policies that we believe are most critical to aid in fully understanding our reported financial results are the following:

Revenue

Revenue from the sale of Ampligen(R) under cost recovery clinical treatment protocols approved by the FDA is recognized when the treatment is provided to the patient.

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Revenues from the sale of product are recognized when the product is shipped, as title is transferred to the customer. We have no other obligation associated with our products once shipment has occurred.

Inventories

We use the lower of first-in, first-out ("FIFO") cost or market method of accounting for inventory.

Patents and Trademarks

Patents and trademarks are stated at cost (primarily legal fees) and are amortized using the straight-line method over the estimated useful life of 17 years. We review our patents and trademark rights periodically to determine whether they have continuing value. Such review includes an analysis of the patent and trademark's ultimate revenue and profitability potential. In addition, management's review addresses whether each patent continues to fit into our strategic business plans.

Stock Based Compensation

Under FAS 123R, share-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the requisite service period. We adopted the provisions of FAS 123R, effective January 1, 2006, using a modified prospective application. Under this method, compensation cost is recognized for all share-based payments granted, modified or settled after the date of adoption, as well as for any unvested awards that were granted prior to the date of adoption. Prior periods are not revised for comparative purposes. Because we previously adopted only the pro forma disclosure provisions of FAS 123, we recognize compensation cost relating to the unvested portion of awards granted prior to the date of adoption, using the same estimate of the grant-date fair value and the same attribution method used to determine the pro forma disclosures under FAS 123, except that forfeiture rates are estimated for all options, as required by FAS 123R. The cumulative effect of applying the forfeiture rates is not material.

The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model. Expected volatility is based on the historical volatility of the price of our common stock. The risk-free interest rate is based on U.S. Treasury issues with a term equal to the expected life of the option. We use uses historical data to estimate expected dividend yield, expected life and forfeiture rates.

Concentration of Credit Risk

Our policy is to limit the amount of credit exposure to any one financial institution and place investments with financial institutions evaluated as being credit worthy, or in short-term money markets, which are exposed to minimal interest rate and credit risks. At and since December 31, 2008, we have had bank deposits and overnight repurchase agreements that exceed federally insured limits.

Concentration of credit risk, with respect to receivables, is limited through our credit evaluation process. We do not require collateral on our receivables. Our receivables consist principally of amounts due from wholesale drug companies as of December 31, 2007 and 2008.

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Sales to three large wholesalers represented approximately 68% and 77% of our total sales for the years ended December 31, 2007 and 2008, respectively.

Item 7A. Quantitative And Qualitative Disclosures About Market Risk.

We had approximately $6,119,000 in cash and cash equivalents at December 31, 2008. To the extent that our cash and cash equivalents exceed our near term funding needs, we invest the excess cash in three to twelve month interest bearing financial instruments. We employ established conservative policies and procedures to manage any risks with respect to investment exposure.

We have not entered into, and do not expect to enter into, financial instruments for trading or hedging purposes.

ITEM 8. Financial Statements and Supplementary Data.

The consolidated balance sheets as of December 31, 2007 and 2008, and our consolidated statements of operations, changes in stockholders' equity and comprehensive loss and cash flows for each of the years in the three year period ended December 31, 2008, together with the report of McGladrey & Pullen, LLP, independent registered public accountants, is included at the end of this report. Reference is made to the "Index to Financial Statements and Financial Statement Schedule" on page F-1.

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures.

None.

ITEM 9A. Controls and Procedures.

Effectiveness of Control Procedures

As of December 31, 2008, the end of the period covered by this report, we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Act of 1934, as amended, as of December 31, 2008. Our disclosure controls and procedures are intended to ensure that the information we are required to disclose in the reports that we file or submit under the Securities Exchange Act of 1934 is (i) recorded, processed, summarized and reported within the time periods specified in the Securities Exchange Commission's rules and forms and (ii) accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as the principal executive and financial officers, respectively, to allow final decisions regarding required disclosures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the controls and procedures were effective as of December 31, 2008 to ensure that material information was accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Our management has concluded that the financial statements included in this Form 10-K present fairly, in all material respects our financial position, results of operations and cash flows for the periods presented in conformity with accounting principles generally accepted in the United States of America.

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Changes in Internal Control over Financial Reporting

We made no changes in our internal control over financial reporting during the last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act).

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rules 13a-15(f) or 15d-15(f), under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, our principal executive and principal financial officers and affected by our Board of Directors, management and other personnel, and to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii)provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the

company's assets that could have a material effect on its financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2008. In making this assessment, management used the criteria set forth in the framework established by the Committee of Sponsoring Organizations of the Treadway Commission Internal Control--Integrated Framework, (COSO). Based on this assessment, management has not identified any material weaknesses as of December 31, 2008. A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

Management has concluded that we did maintain effective internal control over financial reporting as of December 31, 2008, based on the criteria set forth in "Internal Control--Integrated Framework" issued by the COSO.

Our internal control over financial reporting as of December 31, 2008 has been audited by McGladrey and Pullen, LLP, an independent registered public accounting firm, as stated in their report which appears herein.

ITEM 9B. Other Information.

None.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Hemispherx Biopharma, Inc.

We have audited Hemispherx Biopharma, Inc.'s internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control--Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Hemispherx Biopharma, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (a) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (b) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (c) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Hemispherx Biopharma, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008 based on criteria established in Internal Control--Integrated Framework [issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO)].

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the December 31, 2008 consolidated financial statements of Hemispherx Biopharma, Inc. and our report dated March 13, 2009 expressed an unqualified opinion.

Blue Bell, Pennsylvania
March 13, 2009

/s/ McGladrey & Pullen, LLP

PART III

Item 10. Directors and Executive Officers and Corporate Governance.

The following sets forth biographical information about each of our directors and executive officers as of the date of this report:

Name	Age	Position
William A. Carter, M.D.	71	Chairman, Chief Executive Officer
Charles T. Bernhardt, CPA	47	Chief Financial Officer
David R. Strayer, M.D.	63	Medical Director, Regulatory Affairs
Carol A. Smith, Ph.D.	57	VP of Manufacturing Quality and Process Development
Richard C. Piani	80	Director

Thomas K. Equels	58	Director
Katalin Ferencz-Biro	62	Senior Vice President of Regulatory Affairs
William M. Mitchell, M.D.	74	Director
Ransom W. Etheridge	69	Secretary and General Counsel
Iraj Eqhbal Kiani, Ph.D.	61	Director
Wayne Springate	38	Vice President of Operations
Russel Lander	58	Vice President of Quality Assurance

Each director has been elected to serve until the next annual meeting of stockholders, or until his earlier resignation, removal from office, death or incapacity. Each executive officer serves at the discretion of the Board of Directors, subject to rights, if any, under contracts of employment.

WILLIAM A. CARTER, M.D., the co-inventor of Ampligen(R), joined us in 1978, and has served as: (a) our Chief Scientific Officer since May 1989; (b) the Chairman of our Board of Directors since January 1992; (c) our Chief Executive Officer since July 1993; (d) our President since April, 1995; and (e) a director since 1987. From 1987 to 1988, Dr. Carter served as our Chairman. Dr. Carter was a leading innovator in the development of human interferon for a variety of treatment indications including various viral diseases and cancer. Dr. Carter received the first FDA approval to initiate clinical trials on a beta interferon product manufactured in the U.S. under his supervision. From 1985 to October 1988, Dr. Carter served as our Chief Executive Officer and Chief Scientist. He received his M.D. degree from Duke University and underwent his post-doctoral training at the National Institutes of Health and Johns Hopkins University. Dr. Carter also served as Professor of Neoplastic Diseases at Hahnemann Medical University, a position he held from 1980 to 1998. Dr. Carter served as Director of Clinical Research for Hahnemann Medical University's Institute for Cancer and Blood Diseases, and as a professor at Johns Hopkins School of Medicine and the State University of New York at Buffalo. Dr. Carter is a Board certified physician and author of more than 200 scientific articles, including the editing of various textbooks on anti-viral and immune therapy.

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CHARLES T. BERNHARDT is a Certified Public Accountant who also has attained a Masters' Degree in Business Administration. He is a graduate of Villanova University and West Chester University of Pennsylvania who has served as our Chief Financial Officer since January 1, 2009. Most recently he was the Director of Accounting for Healthcare Division of Thomson Reuters, an overall company with $12 billion annual revenues and 50,000 total world-wide employees, where he was responsible for their Healthcare Division's accounting operations, including the Physicians' Desk Reference business, as well as the shared financial services for the Healthcare and Scientific Divisions from 2006 to 2008. He was a Regional Controller for Comcast Cable during 1999 to 2002, Director of Finance for TelAmerica Media for 2003 to 2006 and earlier in his career a member of the Internal Audit management teams American Stores Corporation and ICI Americas/Zenica (currently AstraZenica Pharmaceuticals). In 1986, he became a C.P.A. licensed in Pennsylvania and New Jersey while with public accounting's "Big Four" firm of KPMG.

DAVID R. STRAYER, M.D. who served as Professor of Medicine at the Medical College of Pennsylvania and Hahnemann University, has acted as our Medical Director since 1986. He is Board Certified in Medical Oncology and Internal Medicine with research interests in the fields of cancer and immune system disorders. Dr. Strayer has served as principal investigator in studies funded by

the Leukemia Society of America, the American Cancer Society, and the National Institutes of Health. Dr. Strayer attended the School of Medicine at the University of California at Los Angeles where he received his M.D. in 1972.

CAROL A. SMITH, Ph.D. is Vice President of Manufacturing Quality and Process Development who has served as our Director of Manufacturing and Process Development from 1995 to 2003, as Director of Operations from 1993 to 1995 and as the Manager of Quality Control from 1991 to 1993, with responsibility for the manufacture, quality control, process development, technology transfer to contract manufacturers and the chemistry of Ampligen(R). Dr. Smith was Scientist/Quality Assurance Officer for Virotech International, Inc. from 1989 to 1991 and Director of the Reverse Transcriptase and Interferon Laboratories and a Clinical Monitor for Life Sciences, Inc. from 1983 to 1989. She received her Ph.D. in Medical Sciences with a concentration on Virology from the University of South Florida, College of Medicine in 1980 and was an NIH post-doctoral fellow in the Department of Microbiology and Virology at the Pennsylvania State University College of Medicine from 1980 to 1983.

RICHARD C. PIANI has been a director since 1995. Mr. Piani has been employed as a principal delegate for Industry to the City of Science and Industry, Paris, France, a billion dollar scientific and educational complex. Mr. Piani provided consulting to us in 1993, with respect to general business strategies for our European operations and markets. Mr. Piani served as Chairman of Industrielle du Batiment-Morin, a building materials corporation, from 1986 to 1993. Previously Mr. Piani was a Professor of International Strategy at Paris Dauphine University from 1984 to 1993. From 1979 to 1985, Mr. Piani served as Group Director in Charge of International and Commercial Affairs for Rhone-Poulenc and from 1973 to 1979 he was Chairman and Chief Executive Officer of Societe "La Cellophane", the French company which invented cellophane and several other worldwide products. Mr. Piani has a Law degree from Faculte de Droit, Paris Sorbonne and a Business Administration degree from Ecole des Hautes Etudes Commerciales, Paris.

THOMAS K. EQUELS is the President and Managing Director of Equels Law Firm based in Miami Florida. Mr. Equels legal practice is focused on litigation, with particular emphasis on civil racketeering for about 25 years Mr. Equels has represented national and state government and companies in the banking, insurance, aviation, pharmaceutical and construction industries. Mr. Equels
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received his law degree from Florida State University and he is a graduate of Troy State University. He is a member of the Florida Bar, the American Bar Association and the Academy of Florida Trial Lawyers. Along with serving as a Board member, he continues to serve as the Company's litigation lawyer.

WILLIAM M. MITCHELL, M.D., Ph.D. has been a director since July 1998. Dr. Mitchell is a Professor of Pathology at Vanderbilt University School of Medicine. Dr. Mitchell earned a M.D. from Vanderbilt and a Ph.D. from Johns Hopkins University, where he served as an Intern in Internal Medicine, followed by a Fellowship at its School of Medicine. Dr. Mitchell has published over 200 papers, reviews and abstracts dealing with viruses, anti-viral drugs and immune responses to HIV infection. Dr. Mitchell has worked for and with many professional societies, including the International Society for Antiviral Research, the American Society of Biochemistry and Molecular Biology, the American Society of Microbiology and government review committees, among them the National Institutes of Health, AIDS and Related Research Review Group. Dr. Mitchell previously served as one of our directors from 1987 to 1989.

RANSOM W. ETHERIDGE presently serves as our secretary and general counsel. He served as a member of our Board of Directors from October 1997 through November 2008. Mr. Etheridge first became associated with us in 1980 when he provided consulting services to us and participated in negotiations with respect to our initial private placement through Oppenheimer & Co., Inc. Mr. Etheridge has been practicing law since 1967, specializing in transactional law. Mr. Etheridge is a

member of the Virginia State Bar, a Judicial Remedies Award Scholar, and has served as President of the Tidewater Arthritis Foundation. He is a graduate of Duke University, and received his Law degree from the University of Richmond School of Law.

IRAJ EQHBAL KIANI, M.B.A., Ph.D., was appointed to the Board of Directors on May 1, 2002. Dr. Kiani is a citizen of the United States and England that resides in Newport, California. Dr. Kiani served in various local government positions including the Mayor and Governor of Yasoi, Capital of Boyerahmand, Iran. In 1980, Dr. Kiani moved to England, where he established and managed several trading companies over a period of some 20 years. Dr. Kiani is a planning and logistic specialist who is now applying his knowledge and experience to build a worldwide immunology network, which will use our proprietary technology. Dr. Kiani received his Ph.D. degree from the University of Ferdosi in Iran, ND from American University.

WAYNE S. SPRINGATE is Vice President of Operations and joined Hemispherx in 2002 as Vice President of Business Development. Mr. Springate came on board when Hemispherx acquired Alferon N Injection(R) and its New Brunswick, NJ manufacturing facilities. He led the consolidation of our Rockville facility to our New Brunswick location as well as coordinated the relocation of manufacturing polymers from South Africa to our production facility in New Brunswick. He is responsible for preparing our Manufacturing plant for a Pre Approval Inspection by the FDA in connection with the filing of our Ampligen(R) NDA. Previously, Mr. Springate acted as President for World Fashion Concepts. He oversaw operations at several locations in the United States and overseas. Mr. Springate assisted the CEO in details of operations on a daily basis and was involved in all aspects of manufacturing, warehouse management, distribution and logistics.

KATALIN FERENCZ-BIRO, Ph.D. has served as the Company's Senior Vice President of Regulatory Affairs and Quality Assurance Departments since January 2007. She served as the Director of Regulatory Affairs and Quality Assurance from 2006 to 2007. Previously from 1987 to 2003, she served Interferon Sciences Inc, in
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various positions including Senior Director of Regulatory Affairs, Quality Control and Quality Assurance Departments, and FDA official for our FDA approved product, Alferon N Injection(R). Dr. Ferencz-Biro received her Ph.D. in Chemistry/ Biochemistry in 1972 from the University of Eotvos Lorand, Budapest, Hungary, and her M.S., in Chemistry and Biology in 1971 from University of Eotvos Lorand, Budapest, Hungary. She was a postdoctoral fellow from 1981-1984 in Rutgers University, Center for Alcohol Studies, Piscataway, New Jersey. She is an author and co-author of several scientific publications, patents and presentations on the field of biochemistry. Currently she is a member of Regulatory Affairs Professionals Society.

RUSSEL J. LANDER, Ph.D. is Vice President Quality Assurance. Dr. Lander joined Hemispherx in 2005, assuming responsibility for CMC writing for the NDA filing of Ampligen(R). He has subsequently served at the New Brunswick site as Director of Quality Control and has provided guidance to the efforts to improve and validate the manufacturing process for the synthesis of Ampligen(R) polynucleotide raw materials, Poly I and Poly C12U. Dr. Lander was formerly employed at Merck and Co., Inc. in the process development groups for drug development (1977-1991) and vaccines (1991-2005). Dr. Lander received his Ph.D. in Chemical/Biochemical Engineering from the University of Pennsylvania. He has authored numerous scientific publications and invention disclosures.

On November 27, 2008, Anthony Bonelli, left our employment when his employment agreement ended. Mr. Bonelli was President and Chief Operating Officer of the Company for two years.

Robert E. Peterson, our Chief Financial Officer for nearly 20 years, retired as

of December 31, 2008. Mr. Peterson retains a position of part-time consultant and financial advisor to us.

Compliance with Section 16(a) of the Exchange Act

Section 16(a) of the Exchange Act requires our officers and directors, and persons who own more than ten percent of a registered class of equity securities, to file reports with the Securities and Exchange Commission reflecting their initial position of ownership on Form 3 and changes in ownership on Form 4 or Form 5. Based solely on a review of the copies of such Forms received by us, we found that, during the fiscal year ended December 31, 2008, certain of our officers and directors had not complied with all applicable Section 16(a) filing requirements on a timely basis with regard to transactions occurring in 2008. Specifically, Dr. Carter filed one form 4 late concerning one transaction; Mr. Etheridge filed three forms 4 late concerning three transactions; Mr. Kiani filed three forms 4 late concerning three transactions; Mr. Piani filed three forms 4 late concerning three transactions; Dr. Mitchell filed four forms 4 late concerning four transactions; and Dr. Strayer filed one form 4 late concerning one transaction.

Audit Committee and Audit Committee Expert

The Audit Committee of our Board of Directors consists of Richard Piani, Committee Chairman, William Mitchell, M.D. and Iraj Eqbal Kiani. Mr. Piani, Dr. Mitchell, and Mr. Kiani are all determined by the Board of Directors to be independent directors as required under Section 121B(2)(a) of the NYSE Alternext US Company Guide. We do not have a financial expert as defined in the SEC rules on the committee in the true sense of the description. However, Mr. Piani has 40 years experience in business and has served in senior level and leadership positions for international businesses. His working experience includes reviewing and analyzing financial statements and dealing with financial

institutions. We believe Mr. Piani, Dr. Mitchell, and Mr. Kiani to be independent of management and free of any relationship that would interfere with their exercise of independent judgment as members of this committee. The principal functions of the Audit Committee are to (i) assist the Board in fulfilling its oversight responsibility relating to the annual independent audit of our consolidated financial statements and internal control over financial reporting, the engagement of the independent registered public accounting firm and the evaluation of the independent registered public accounting firm's qualifications, independence and performance, (ii) prepare the reports or statements as may be required by NYSE Alternext US or the securities laws, (iii) assist the Board in fulfilling its oversight responsibility relating to the integrity of our financial statements and financial reporting process and our system of internal accounting and financial controls, (iv) discuss the financial statements and reports with management, including any significant adjustments, management judgments and estimates, new accounting policies and disagreements with management, and (v) review disclosures by our independent registered public accounting firm concerning relationships with us and the performance of our independent accountants.

Code of Ethics

Our Board of Directors adopted a code of ethics and business conduct for officers, directors and employees that went into effect on May 19, 2003. This code has been presented, reviewed and signed by each officer, director and employee. You may obtain a copy of this code by visiting our web site at www.hemispherx.net (Corporate Info) or by written request to our office at 1617 JFK Boulevard, Suite 660, Philadelphia, PA 19103.

Item 11. Executive Compensation.

Compensation Discussion and Analysis

Objectives and Philosophy of Executive Compensation

The primary objectives of the compensation committee of our board of directors with respect to executive compensation are to attract and retain the most talented and dedicated executives possible, to tie annual and long-term cash and stock incentives to achievement of measurable performance objectives, and to align executives' incentives with stockholder value creation. To achieve these objectives, the compensation committee expects to implement and maintain compensation plans that tie a substantial portion of executives' overall compensation to key strategic financial and operational goals such as the establishment and maintenance of key strategic relationships, the development of our products, the identification and advancement of additional product and the performance of our common stock price. The compensation committee evaluates individual executive performance with the goal of setting compensation at levels the committee believes are comparable with executives in other companies of similar size and stage of development operating in the biotechnology industry while taking into account our relative performance and our own strategic goals.

Our compensation plans are developed by utilizing publicly available compensation data and subscription compensation survey data for national and regional companies in the biopharmaceutical industry. We believe that the practices of this group of companies provide us with appropriate compensation benchmarks, because these companies have similar organizational structures and tend to compete with us for executives and other employees. For benchmarking executive compensation, we typically review the compensation data we have

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collected from the complete group of companies, as well as a subset of the data from those companies that have a similar number of employees as our company. In past years, we had engaged independent outside consultants to help us analyze this data and to compare our compensation programs with the practices of the companies represented in the compensation data we review. However given the current harsh economic conditions and our efforts to conserve cash, we did not undertake an analysis of any compensation nor offer any incremental or performance salary increases for the year-end 2008. Additionally, the Board did not approve the award of any bonus for 2008.

Elements of Executive Compensation

Executive compensation consists of the following elements:

Base Salary

Base salaries for our executives are established based on the scope of their responsibilities, taking into account competitive market compensation paid by other companies for similar positions. Generally, we believe that executive base salaries should be targeted near the median of the range of salaries for executives in similar positions with similar responsibilities at comparable companies, in line with our compensation philosophy. Base salaries are reviewed annually, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. This review normally occurs in the fourth quarter of each year.

Annual Bonus

Our compensation program includes eligibility for an annual performance-based cash bonus in the case of all executives and certain senior, non-executive employees. The amount of the cash bonus depends on the level of achievement of the stated corporate, department, and individual performance goals, with a target bonus generally set as a percentage of base salary. As provided in his employment agreement, our Chief Executive Officer is eligible

for an annual performance-based bonus up to 25% of their salaries, the amount of which, if any, is determined by the board of directors in its sole discretion based on the recommendation of the compensation committee.

The compensation committee utilizes annual incentive bonuses to compensate officers for achieving financial and operational goals and for achieving individual annual performance objectives. These objectives will vary depending on the individual executive, but will relate generally to strategic factors such as establishment and maintenance of key strategic relationships, development of our product, identification and research and development of additional products, and to financial factors such as raising capital and improving our results of operations.

The Compensation Committee and the Board of Directors declined to awarded bonuses for 2008 to any of our executives, senior or non-executive employees.

Long-Term Incentive Program

We believe that long-term performance is achieved through an ownership culture that encourages such performance by our executive officers through the use of stock and stock-based awards. Our stock plans have been established to provide our employees, including our executive officers, with incentives to help align those employees' interests with the interests of stockholders. The
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compensation committee believes that the use of stock and stock-based awards offers the best approach to achieving our compensation goals. We have historically elected to use stock options as the primary long-term equity incentive vehicle. We have adopted stock ownership guidelines and our stock compensation plans have provided the principal method, other than through direct investment for our executive officers to acquire equity in our Company. We believe that the annual aggregate value of these awards should be set near competitive median levels for comparable companies. However, in the early stage of our business, we provided a greater portion of total compensation to our executives through our stock compensation plans than through cash-based compensation.

Stock Options

Our stock plans authorize us to grant options to purchase shares of common stock to our employees, directors and consultants. Our compensation committee oversees the administration of our stock option plan. The compensation committee reviews and recommends approval by our Board of Directors of stock option awards to executive officers based upon a review of competitive compensation data, its assessment of individual performance, a review of each executive's existing long-term incentives, and retention considerations. Periodic stock option grants are made at the discretion of the Board of Directors upon recommendation of the compensation committee to eligible employees and, in appropriate circumstances, the compensation committee considers the recommendations of members of management. In 2008, the Compensation Committee and the Board authorized the renewal of expiring options for certain named executives in the amounts indicated in the section entitled "Stock Option Grants to Executive Officers." Grants were made to certain of our employees based on past performance, particularly, those who worked hard and diligently on the preparation of our NDA. Stock options granted by us have an exercise price equal to the fair market value of our common stock on the day of grant and typically vest over a period of years based upon continued employment, and generally expire ten years after the date of grant. Incentive stock options also include certain other terms necessary to assure compliance with the Internal Revenue Code of 1986, as amended, or Internal Revenue Code.

We expect to continue to use stock options as a long-term incentive

vehicle because: (1) Stock options align the interests of executives with those of the shareholders, support a pay-for-performance culture, foster employee stock ownership, and focus the management team on increasing value for the shareholders, (2) Stock options are performance based. All the value received by the recipient of a stock option is based on the growth of the stock price, (3) Stock options help to provide a balance to the overall executive compensation program as base salary and our discretionary annual bonus program focus on short-term compensation, while the vesting of stock options increases shareholder value over the longer term, and (4) the vesting period of stock options encourages executive retention and the preservation of shareholder value.

In determining the number of stock options to be granted to executives, we take into account the individual's position, scope of responsibility, ability to affect profits and shareholder value and the individual's historic and recent performance and the value of stock options in relation to other elements of the individual executive's total compensation.

Options granted under the 2004 plan include 1,345,742 in 2006, 3,232,870 in 2007 (including 2,970,000 issued for expiring options) and 687,000 in 2008 (302,000 issued for unexercised and expired options). Unless sooner terminated, the Equity Incentive Plan will continue in effect for a period of 10 years from its effective date.

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Our 2004 Equity Compensation Plan authorizes us to grant restricted stock and restricted stock units. In 2008, we issued 755,829 shares to consultants and vendors for services rendered in lieu of cash.

As of December 31, 2008 we had 18,081 shares for future use under the 2004 plan.

On June 30, 2007 the stockholders adopted the 2007 Equity Incentive Plan which authorizes the issuance of up to 8,000,000 stock options to acquire common stock pursuant to the terms of the plan. This Plan also authorizes us to grant restricted stock and restricted stock units. 1,450,000 options (all were issued for expiring and unexercised options) were granted pursuant to the 2007 plan. In addition, we issued 201,010 shares of unrestricted stock and 2,434,177 shares in restricted stock to consultants and other vendors for services performed in lieu of cash.

Other Compensation

Our Chief Executive Officer, Chief Financial Officer and General Counsel have employment, and/or engagement contracts that will remain in effect until they are terminated, expire, or are renegotiated. Each contract is different with respect to specific benefits or other compensation. We maintain a broad-based benefits program that is provided to all employees including vacation, sick leave and health insurance. Details of these agreements is discussed below. Notwithstanding the disclosure below, the executive officers are participating in the Employee Wage Or Hours Reduction Program (please see "Item 11. Executive Compensation; Compensation Discussion and Analysis; Elements of Executive Compensation; Other Compensation").

Dr. Carter's employment as our Chief Executive Officer and Chief Scientific Officer expires December 31, 2010 unless sooner terminated for cause or disability. The agreement automatically renews for successive one year periods after the initial termination date unless we or Dr. Carter give written notice otherwise at least ninety days prior to the termination date or any renewal period. Dr. Carter has the right to terminate the agreement on 30 days' prior written notice. The base salary is subject to adjustments and the average increase or decrease in the Consumer Price Index for the prior year. In addition, Dr. Carter could receive an annual performance bonus of up to 25% of

his base salary, at the sole discretion of the Compensation Committee of the board of directors, based on his performance or our operating results. Dr. Carter will not participate in any discussions concerning the determination of his annual bonus. Dr. Carter is also entitled to an incentive bonus of 0.5% of the gross proceeds received by us from any joint venture or corporate partnering arrangement. Dr. Carter's agreement also provides that he be paid a base salary and benefits through the last day of the then term of the agreement if he is terminated without "cause", as that term is defined in agreement. In addition, should Dr. Carter terminate the agreement or the agreement be terminated due to his death or disability, the agreement provides that Dr. Carter be paid a base salary and benefits through the last day of the month in which the termination occurred and for an additional twelve month period. On January 1, 2009, Dr. Carter's compensation as an employee was changed pursuant to our "Employee Wage Or Hours Reduction Program" consistent with an employee earning over $200,000 per annum to receive 50% of his wages in Incentive Rights on a three-to-one conversion basis.

Our engagement of Dr. Carter as a consultant related to patent development, as one of our directors and as chairman of the Executive Committee

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of our Board of Directors expires December 31, 2010 unless sooner terminated for cause or disability. The agreement automatically renews for successive one year periods after the initial termination date or any renewal period. Dr. Carter has the right to terminate the agreement on 30 days' prior written notice. The base fee is subject to annual adjustments equal to the percentage increase or decrease of annual dollar value of directors' fees provided to our directors during the prior year. The annual fee is further subject to adjustment based on the average increase or decrease in the Consumer Price Index for the prior year. In addition, Dr. Carter could receive an annual performance bonus of up to 25% of his base fee, at the sole direction of the Compensation Committee of the board of directors, based on his performance. Dr. Carter will not participate in any discussions concerning the determination of this annual bonus. Dr. Carter's agreement also provides that he be paid his base fee through the last day of the then term of the agreement if he is terminated without "cause", as that term is defined in the agreement. In addition, should Dr. Carter terminate the agreement or the agreement be terminated due to his death or disability, the agreement provides that Dr. Carter be paid fees due him through the last day of the month in which the termination occurred and for an additional twelve month period. On January 1, 2009, Dr. Carter's compensation as a consultant was changed pursuant to our "Employee Wage Or Hours Reduction Program" consistent with an employee earning over $200,000 per annum to receive 50% of his fee in Incentive Rights on a three-to-one conversion basis.

An Engagement Agreement with Charles T. Bernhardt, CPA as Chief Financial Officer (interim) was finalized on December 1, 2008 and effective January 1, 2009. The agreement calls for an initial salary of $160,000 per annum and eligibility for the Goal Achievement Incentive Program. Additionally, the agreement is based on an employment "at will" basis in which either party may cancel upon two weeks written notice. Consistent with the Company's "Employee Wage Or Hours Reduction Program", Mr. Bernhardt has elected to receive 50% of his wages in Incentive Rights on a three-to-one conversion basis.

Our agreement with Ransom W. Etheridge provides for Mr. Etheridge's engagement as our General Counsel until December 31, 2009 unless sooner terminated for cause or disability. The agreement automatically renews for successive one year periods after the initial termination date unless we or Mr. Etheridge give written notice otherwise at least ninety days prior to the termination date or any renewal period. Mr. Etheridge has the right to terminate the agreement on 30 days' prior written notice. The initial annual fee for services is $105,408 and is annually subject to adjustment based on the average increase or decrease in the Consumer Price Index for the prior year. Mr. Etheridge's agreement also provides that he be paid all fees through the last

day of then current term of the agreement if he is terminated without "cause" as that term is defined in the agreement. In addition, should Mr. Etheridge terminate the agreement or the agreement be terminated due to his death or disability, the agreement provides that Mr. Etheridge be paid the fees due him through the last day of the month in which the termination occurred and for an additional twelve month period. Mr. Etheridge will devote approximately 85% of his business time to our business. Effective January 1, 2009, one-half of the monthly fee compensation to be paid to Ransom W. Etheridge pursuant to the terms of his Engagement Agreement with us as our General Counsel will be paid in shares of the Company's common stock ("Etheridge Share Compensation"). The number of shares issued as Etheridge Share Compensation shall be calculated based on a value equal to three times one-half of the monthly fee compensation to be paid to Mr. Etheridge pursuant to the terms of his Engagement Agreement with us, with the value of the shares being determined by the closing share price of our common stock on the NYSE Alternext US on the last trading day of each month.

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Goal Achievement Incentive Program

On November 17, 2008 the Board of Directors authorized the Goal Achievement Incentive Program. This program is designed to intensify the efforts of the parties involved in securing strategic partnering agreements with third parties. We will pay the parties participating in the Program an incentive bonus for each timely agreement (as defined below) entered into by us with any and all third parties in which we receive cash (as defined below) from such third parties as a result of the execution of such agreements ("Strategic Partnering Agreements"), provided, however, Strategic Partnering Agreements shall not include agreements whereby we receive cash as a result of (i) only the sale of Ampligen(R) or other Hemispherx products, (ii) our only being reimbursed for expenses, not including expenses for prior research conducted by us, incurred by us, (iii) an agreement in which the only economic benefit to us is one or more loans, and (iv) an agreement, other than an agreement which results in a change of control of Hemispherx, in which the only economic benefit to us is the sale of our equity or other securities. The incentive bonus shall be in an amount equal to one percent (1%) of the amount of all cash received by us pursuant to each such Strategic Partnering Agreement between the dates of the execution of each such Strategic Partnering Agreement and the first commercial sale of Ampligen(R) following the full commercial approval of the sale of Ampligen(R) in each jurisdiction. All incentive bonus payments shall be payable in readily available funds within ten (10) days following receipt by us of readily available funds as a result of our receipt of such first cash. For purposes hereof "timely agreements" means all agreements entered into by us with any and all third parties (a) on or before June 30, 2009 and (b) on or before March 31, 2010 with third parties with which we had been in active negotiations on or before June 30, 2009. For purposes hereof "cash" means any asset which is either (a) readily available funds or (b) capable of being converted into readily available funds in value equal to the value ascribed to such asset in the Strategic Partnering Agreement within six months of the receipt of such asset by the Company. This program presently includes Dr. William Carter, CEO, Dr. Chaunce Bogard, consultant and acting Senior Vice President, The Sage Group (one of our strategic advisors) and Anthony Bonelli, our former President and COO, Dr. David R. Strayer, Medical Director and all of our active employees as of January 1, 2009.

Employee Wage Or Hours Reduction Program

In an effort to conserve Company cash, the Employee Wage Or Hours Reduction Program (the "Program") was ratified by the Board effective January 1, 2009. In a mandatory program that is estimated to be in effect for up to six months, compensation of all active full-time employees as of January 1, 2009 ("Participants") were reduced through a reduction in their wages for which they would be eligible to receive shares of our common stock ("Stock") six months

after the shares were earned. While all employees were also offered the option to reduce their work hours with a proportional decease in wages, none elected this alternative.

On a semi-monthly basis, Participants receive rights to Stock ("Incentive Rights") that cannot be traded. Six months after the date the Incentive Rights are awarded, we will undertake a process to have Incentive Rights converted into Stock and issued to each Participant on a monthly basis. We will establish and maintain a record for the number of Incentive Rights awarded to each Participant. At the end of each semi-monthly period, we will determine the number of Incentive Rights by converting the proportionate

incentive award to the value of the Stock by utilizing the closing price of the Stock on the NYSE Alternext US (formerly the American Stock Exchange or AMEX) based on the average daily closing price for the period.

The Plan is being administered for full-time employees as follows:

- Twenty-three employees earning $90,000 or less per year elected a wage reduction of 10% per annum and are receiving an incentive of two times the value in Stock;
- Four employees earning $90,001 to $200,000 per year elected a wage reduction of 25% per annum are receiving an incentive of two times the value in Stock;
- Two employees earning over $200,000 per year elected a wage reduction of 50% per annum and are receiving an incentive of three times the value in Stock;
- Any employee could elect a 50% per annum wage reduction for which would allow them to be eligible for an incentive award of three times the value of Stock. This option was elected by three employees.

Prior to the Stock being issued, we will establish a trading account with an independent brokerage firm for each Participant. Incentive Rights will constitute income to the Participants and be subject to payroll taxes upon Stock issuance. At a brokerage firm selected by us, we will bear all expenses related to selling the Stock (i.e.; broker fees, transaction costs, commissions, etc.) for payroll withholding taxes purposes. Thereafter, for each Participant during the period that they remain an active employee, we will continue to bear such costs from this designated brokerage firm for the maintenance of this account and all expenses related to selling our Stock. Participants leaving us or voluntarily separating from the Plan will receive the Stock earned upon the six month conversion of their Incentive Rights. The Plan benefits for individuals that are no longer Participants will become fixed and we will not continue to bear such costs from the designated brokerage firm for the maintenance of an account nor any expenses related to selling the Stock except for the initial costs associated to the selling of Stock for payroll withholding taxes purposes.

Employee Bonus Pool Program

An element of the Employee Wage Or Hours Reduction Program was the establishment of a Bonus Pool (the "Pool") in the case of FDA Approval ("Approval") of Ampligen(R). This bonus is to award to each employee of record at January 1, 2009 a pretax sum of 30% in wages, calculated on their base per annum compensation at the time of the Approval, and awarded within three months of Approval. Participants who terminate their employment prior to the Approval will not qualify for this bonus.

Key Employee Retention

The Board of Directors, deeming it essential to the best interests of our shareholders to foster the continuous engagement of key management personnel and recognizing that, as is the case with many publicly held corporations, a change of control might occur and that such possibility, and the uncertainty and questions which it might raise among management, might result in the departure or distraction of management personnel to the detriment of us and our shareholders, determined to reinforce and encourage the continued attention and dedication of members of our management to their engagement without distraction in the face of potentially disturbing circumstances arising from the possibility of a change in control of our Company and entered into identical agreements
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regarding change in control with William A. Carter, our Chief Executive Officer and Chief Scientific Officer and Ransom W. Etheridge, our General Counsel. Each of the agreements regarding change in control became effective March 11, 2005 and continue through December 31, 2008 and shall extend automatically to the third anniversary thereof unless we give notice to the other party prior to the date of such extension that the agreement term will not be extended. Notwithstanding the foregoing, if a change in control occurs during the term of the agreements, the term of the agreements will continue through the second anniversary of the date on which the change in control occurred. Each of the agreements entitles William A. Carter and Ransom W. Etheridge, respectively, to change of control benefits, as defined in the agreements and summarized below, upon their respective termination of employment/engagement with us during a potential change in control, as defined in the agreements or after a change in control, as defined in the agreements, when their respective terminations are caused (1) by us for any reason other than permanent disability or cause, as defined in the agreement (2) by William A. Carter and/or Ransom W. Etheridge, respectively, for good reason as defined in the agreement or, (3) by William A. Carter and/or Ransom W. Etheridge, respectively for any reason during the 30 day period commencing on the first date which is six months after the date of the change in control.

The benefits for each of the foregoing executives would be as follows:
o A lump sum cash payment of three times his base salary and annual bonus amounts; and o Outplacement benefits.

Each agreement also provides that the executive is entitled to a "gross-up" payment to make him whole for any federal excise tax imposed on change of control or severance payments received by him.

Dr. Carter's agreement also provides for the following benefits:
o Continued insurance coverage through the third anniversary of his termination; and o Retirement benefits computed as if he had continued to work for the above period.

On December 31, 2008, we entered into a severance/consulting agreement with retiring Chief Financial Officer, Robert E. Peterson. This agreement provide a monthly fee of $4,000 plus travel expenses and Options to purchase 20,000 shares of the our common stock at the end of each calendar quarter through year-end 2011 in return for consulting services. The exercise price of the Options is to be equal to 120% of the closing price of the our stock on the NYSE Alternext on the last trading day of the calendar quarter for which the Options are being issued. Peterson may terminate the Advisory Services at any time upon giving us Sixty (60) days notice in writing of the intention to terminate the Advisory Services. Please see "Note (12) Royalties, License, and Employment Agreements" of Notes To Consolidated Financial Statements.

401(K) Plan

In December 1995, we established a defined contribution plan, effective January 1, 1995, entitled the Hemispherx Biopharma employees 401(K) Plan and

Trust Agreement. All of our full time employees are eligible to participate in the 401(K) plan following one year of employment. Subject to certain limitations imposed by federal tax laws, participants are eligible to contribute up to 15% of their salary (including bonuses and/or commissions) per annum. Through March 14, 2008, Participants' contributions to the 401(K) plan were matched by Hemispherx at a rate determined annually by the board of directors. Each
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participant immediately vests in his or her deferred salary contributions, while our contributions will vest over one year. Please see Note 11 to the consolidated financial statements contained herein.

Effective March 15, 2008, we ended our 100% matching of up to 6% of the 401(k) contributions provided to the account for each eligible participant. Our 401(k) Plan contribution cost for the twelve months ended December 31, 2008 is $20,421 and it is required for payment prior to the final filing of our 2008 Federal Corporate Tax filing. There has not been any additional Company matching costs since March 15, 2008 and none is projected for calendar year 2009.

Severance

Upon termination of employment, most executive officers are entitled to receive severance payments under their employment and/or engagement agreements. In determining whether to approve and setting the terms of such severance arrangements, the compensation committee recognizes that executives, especially highly ranked executives, often face challenges securing new employment following termination. The employment agreement with our CEO, which expires on December 31, 2010, provides that we pay him an annual salary through the term of the agreement if terminated without cause.

We believe that our Executive Officers' severance package is generally in line with severance packages offered to chief executive officers of the companies of similar size to us represented in the compensation data we reviewed.

Compensation of Directors

Non-employee Board member compensation consists of an annual retainer ("Directors' fees") of $150,000, which in 2008 was paid two thirds in cash and one third in our common stock. On September 9, 2003, the Directors approved a 10 year plan which authorizes up to 1,000,000 shares for use in supporting this compensation plan. The number of shares paid shall have a value of $12,500 with the value of the shares being determined by the closing price of our common stock on the NYSE Alternext US Exchange on the last day of the calendar quarter. Director's fees are paid quarterly at the end of each calendar quarter.

On November 28, 2009, Thomas K. Equels joined our Board of Directors as a non-employee Board member in which his compensation of $150,000 for all director fees were agreed to be paid in the form of our common stock.

All Directors have been granted options to purchase common stock under our Stock Option Plans and/or Warrants to purchase common stock. We believe such compensation and payments are necessary in order for us to attract and retain qualified outside directors.

Commencing as of January 1, 2009, the ratio of stock to cash being paid as Director's fees ("Annual Compensation") was changed. The Annual Compensation for each of the directors then serving, other than Thomas Equels, consists of $25,000 and shares of common stock having a value of $125,000 ("Share Compensation"). The Annual Compensation for Thomas Equels consists of shares of common stock having a value of $150,000 ("Share Compensation").
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To the extent that Share Compensation would exceed 1,000,000 shares in

the aggregate for the ten year period commencing January 1, 2003 as previously approved by Resolution of the Board of September 9, 2003, shares for Share Compensation shall be issued under the our 2007 Equity Incentive Plan.

Summary Compensation Table - 2006

Name and Principal Position	Salary/Fees	Bonus	Stock Award	Option Award (1)	Non-Equity Incentive Plan Compensation	Change in Pens Value and Nonqualified Deferred Compensation Earnings
W. A. Carter, CEO	$655,686	$166,624	-	$1,236,367	-	-
A. Bonelli, COO	35,000(4)	50,000	-	122,601	-	-
R. E. Peterson, CFO	259,164	64,791	-	373,043	-	-
D. Strayer, Medical Director	225,144	-	-	19,200	-	-
M. J. Liao, Director - QC	158,381	-	-	9,600	-	-
C. Smith, VP of MFG	143,136	-	-	9,600	-	-
R. Hansen, VP of Manufacturing	140,311	-	-	9,600	-	-
R. D. Hulse	105,000	-	-	-	-	-

Notes:

(1) Based on Black Scholes Pricing Model of valuing options. Total Fair Value of Option Awards granted to officers in 2006 was $1,780,011.

(2) Consists of Healthcare premiums, life insurance premiums, 401-K matching funds, qualifying insurance premium, company car and parking cost.

(3) Consists of healthcare premiums and 401-K matching funds.

(4) Mr. Bonelli joined us on November 27, 2006. His annual salary is $350,000.

Summary Compensation Table - 2007

Name and Principal Position	Salary/Fees	Bonus	Stock Award	Option Award (1)	Non-Equity Incentive Plan Compensation	Change in Pens Value and Nonqualified Deferred Compensation Earnings
W. A. Carter, CEO	$637,496	$166,156	-	$1,688,079	-	-
A. Bonelli, COO	350,000(4)	87,500	-	59,684	-	-
R. E. Peterson, CFO	259,164	64,791	-	153,055	-	-
D. Strayer, Medical Director	240,348	50,347	-	79,810	-	-
C. Smith, VP of MFG.	147,695	-	-	34,235	-	-
K. Ferencz-Biro, VP of Reg. Affairs	145,000	-	-	11,744	-	-
W. Springate, VP of Operations	150,000	37,500	-	36,253	-	-
R. Lander, VP of Quality Assurance	178,000	-	-	11,744	-	-

Notes:

(1) Based on Black Scholes pricing model of valuing options. Total fair of options granted to Officers in 2007 was $2,241,028.

(2) Consists of a) Life Insurance premiums totaling $63,627; b) 401-K matching funds of $18,833; c) Healthcare premiums of $28,586; and d) Company car expenses of $12,017.

(3) Healthcare premiums of $9,649, car allowance expense of $9,276, and life insurance premiums totaling $14,400.

(4) Consists of Healthcare premiums of $21,266, and 401-K matching funds of $8,862.

(5) Healthcare premiums and 401-K matching funds.

(6) Healthcare premiums.

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Summary Compensation Table - 2008

Name and Principal Position	Salary/Fees	Bonus	Stock Award	Option Award (1)	Non-Equity Incentive Plan Compensation	Change in Pens Value and Nonqualified Deferred Compensation Earnings
W. A. Carter, CEO	$664,624	$-	-	$316,571(4)	-	-
R. E. Peterson, CFO (3)	259,164	-	-	-	-	-
D. Strayer, Medical Director	201,389	-	-	16,168(4)	-	-
C. Smith, VP of MFG.	147,695	-	-	600(4)	-	-
K. Ferencz-Biro, VP of Reg. Affairs	145,000	-	-	-	-	-
W. Springate, VP of Operations	150,000	-	-	-	-	-
R. Lander, VP of Quality Assurance	178,000	-	-	-	-	-

Notes:

(1) Based on Black Scholes pricing model of valuing options. Total fair of options granted to Officers in 2007 was $364,648.

(2) Consists of a) Life Insurance premiums totaling $66,411; b) Healthcare premiums of $28,586; and d) Company car expenses of $11,097.

(3) Mr. Peterson retired from the Company Effective December 31, 2008.

(4) Issue of options for options previously granted that expired unexercised.

(5) Consists of Healthcare premiums of $21,226, and 401-K matching funds of $1,846.

(6) Healthcare premiums and 401-K matching funds.

(7) Healthcare premiums.

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2007 Stock Option Grants to Executive Officers

The following table provides additional information about option awards granted to our Named Executive Officers during the year ended December 31, 2007. The compensation plan under which the grants in the following tables were made are described in the Compensation Discussion and Analysis section headed "Long-Term Equity Incentive Awards".

Name	Grant Date	No. of Options	Exercise Price per Share	Expiration Date	Closing Grant
W.A. Carter, CEO	9/10/07	1,000,000(1)	$2.00	9/9/17	1.2
	10/1/07	1,400,000(1)	3.50	9/30/17	1.6
A. Bonelli, COO	2/22/07	50,000	2.07	2/27/17	1.8
R.E. Peterson, CFO	1/23/07	13,750(1)	2.37	1/23/17	2.1
	9/10/07	200,000(1)	2.00	9/9/17	1.2
D. Strayer, Medical Director	1/23/07	20,000(1)	2.37	1/23/17	2.1
	9/10/07	50,000(1)	2.00	9/9/17	1.2
	12/6/07	25,000	1.30	12/6/17	1.3
C. Smith, VP of MFG.	1/23/07	6,791(1)	2.37	1/23/17	2.1
	9/10/07	20,000(1)	2.00	9/9/17	1.2
	12/6/07	15,000	1.30	12/6/17	1.3
W. Springate, VP of Operations	5/1/07	20,000	1.78	4/30/17	1.6
	12/6/07	20,000	1.30	12/6/17	1.3
K. Ferencz-Biro, VP of Reg. Affairs	12/6/07	15,000	1.30	12/6/17	1.3
R. Lander, VP of Quality Assurance	12/6/07	15,000	1.30	12/6/17	1.3

1) Renewal of previously issued options that expired unexercised.

2) These amounts shown represent the approximate amount we recognize for financial statement reporting purposes in fiscal year 2007 for the fair value of equity awards granted to the named executive officers. As a result, these amounts do not reflect the amount of compensation actually received by the named executive officer during the fiscal year. For a description of the assumptions used in calculating the fair value of equity awards under SFAS No. 123(R), see Note 2(m) of our financial statements.

2008 Stock Option Grants to Executive Officers

The following table provides additional information about option awards granted to our Named Executive Officers during the year ended December 31, 2008. The compensation plan under which the grants in the following tables were made are described in the Compensation Discussion and Analysis section headed "Long-Term Equity Incentive Awards".

Name	Grant Date	No. of Options	Exercise Price per Share	Expiration Date	Closing Grant
W.A. Carter, CEO	2/18/08	190,000(1)	$4.00	2/18/18	0.
	9/17/08	1,450,000(1)	2.20	9/17/18	0.
D. Strayer, Medical Director	2/18/08	50,000(1)	4.00	2/18/18	0.
C. Smith, VP MFG.	2/18/08	5,000(1)	4.00	2/18/18	0.

1) Renewal of previously issued options that expired unexercised.

2) These amounts shown represent the approximate amount we recognize for financial statement reporting purposes in fiscal year 2008 for the fair value of equity awards granted to the named executive officers. As a result, these amounts do not reflect the amount of compensation actually received by the named executive officer during the fiscal year. For a description of the assumptions used in calculating the fair value of equity awards under SFAS No. 123(R), see Note 2(m) of our financial statements.

Outstanding Equity Awards at Year End - 2007

	Option/Warrants Awards							
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Ma Va Sh Un Ha Ve
W.A. Carter, CEO	1,450,000	0	0	$2.20	9/8/08	-	
	1,000,000	0	0	2.00	9/9/17	-	

	190,000	0	0	4.00	1/1/08	-	
	3,728	0	0	2.71	12/31/10	-	
	10,000	0	0	4.03	1/3/11	-	
	167,000	0	0	2.60	9/7/14	-	
	153,000	0	0	2.60	12/7/14	-	
	100,000	0	0	1.75	4/26/15	-	
	465,000	0	0	1.86	6/30/15	-	
	70,000	0	0	2.87	12/9/15	-	
	300,000	0	0	2.38	1/1/16	-	
	10,000	0	0	2.61	12/9/15	-	
	376,650	0	0	3.78	2/22/16	-	
	1,400,000	0	0	3.50	9/30/17	-	
A. Bonelli, COO	100,000	0	0	2.11	11/26/16	-	
	50,000	0	0	2.07	2/27/17	-	
R. Peterson, CFO	200,000	0	0	2.00	9/9/17	-	
	50,000	0	0	3.44	6/22/14	-	
	13,824	0	0	2.60	9/7/14	-	
	55,000	0	0	1.75	4/26/15	-	
	10,000	0	0	2.61	12/8/15	-	
	50,000	0	0	3.85	2/28/16	-	
	100,000	0	0	3.48	4/14/16	-	
	30,000	0	0	3.55	4/30/16	-	
	13,750	0	0	2.37	1/22/17	-	
	10,000	0	0	4.03	1/3/11	-	
D. Strayer, Medical Director	50,000	0	0	2.00	9/9/17	-	
	50,000	0	0	4.00	2/28/08	-	
	10,000	0	0	4.03	1/3/11	-	
	20,000	0	0	3.50	2/23/07	-	
	10,000	0	0	1.90	12/14/14	-	
	10,000	0	0	2.61	12/8/15	-	
	10,000	5,000	0	2.20	11/20/16	-	
	25,000	0	0	1.30	12/6/17	-	
C. Smith, VP of MFG	20,000	0	0	2.00	9/9/17	-	
	5,000	0	0	4.00	9/17/18	-	
	10,000	0	0	4.03	1/3/11	-	
	10,000	0	0	2.61	12/8/15	-	
	6,791	0	0	2.37	1/23/17	-	
	10,000	0	0	1.90	12/7/14	-	
	5,000	2,500	0	2.20	11/20/16	-	
W. Springate, VP of Operations	1,812	0	0	1.90	12/7/14	-	
	2,088	0	0	2.61	12/8/05	-	
	5,000	0	0	2.20	11/20/16	-	
	20,200	0	0	1.78	4/30/17	-	
	6,067	13,333	0	1.30	12/6/17	-	
R. Lander, VP of Quality Assurance	5,000	10,000	0	1.30	12/6/17	-	
K. Ferencz-Biro, VP of Reg. Affairs	5,000	10,000	0	1.30	12/6/17	-	

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Outstanding Equity Awards at Year End - 2008

	Option/Warrants Awards							
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Ma Va Sh Un Ha Ve
W.A. Carter, CEO	1,450,000	0	0	$2.20	9/17/18	-	
	1,000,000	0	0	2.00	9/9/17	-	
	190,000	0	0	4.00	2/18/18	-	
	73,728	0	0	2.71	12/31/10	-	
	10,000	0	0	4.03	1/3/11	-	
	167,000	0	0	2.60	9/7/14	-	
	153,000	0	0	2.60	12/7/14	-	
	100,000	0	0	1.75	4/26/15	-	
	465,000	0	0	1.86	6/30/15	-	
	70,000	0	0	2.87	12/9/15	-	
	300,000	0	0	2.38	1/1/16	-	
	10,000	0	0	2.61	12/9/15	-	
	376,650	0	0	3.78	2/22/16	-	
	1,400,000	0	0	3.50	9/30/17	-	
C. Bogard, S VP	100,000	0	0	0.68	6/5/13	-	
	50,000	0	0	2.07	2/27/17	-	
R. Peterson, CFO	200,000	0	0	2.00	9/9/17	-	
	50,000	0	0	3.44	6/22/14	-	
	13,824	0	0	2.60	9/7/14	-	
	55,000	0	0	1.75	4/26/15	-	
	10,000	0	0	2.61	12/8/15	-	
	50,000	0	0	3.85	2/28/16	-	
	100,000	0	0	3.48	4/14/16	-	
	30,000	0	0	3.55	4/30/16	-	
	13,750	0	0	2.37	1/22/17	-	
	10,000	0	0	4.03	1/3/11	-	
D. Strayer, Medical Director	50,000	0	0	2.00	9/9/17	-	
	50,000	0	0	4.00	2/28/18	-	
	10,000	0	0	4.03	1/3/11	-	
	5,000	15,000	0	3.50	2/23/07	-	
	10,000	0	0	1.90	12/14/14	-	
	10,000	0	0	2.61	12/8/15	-	
	15,000	0	0	2.20	11/20/16	-	
	16,667	8,333	0	1.30	12/6/17	-	
C. Smith, VP of	20,000	0	0	2.00	9/9/17	-	